PATIENT RADIATION DOSE RANGES FOR PROCEDURES IN UNIVERSITAS HOSPITAL VASCULAR LABORATORIES

Henra Muller

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Supervisor: PROF H FRIEDRICH-NEL

Co-supervisor: PROF WID RAE

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DEDICATION

I dedicate this dissertation to my father, Johannes Malan (13 September 1935 – 10 August 2012). You always encouraged me to learn more and better myself. Thank you for the wonderful father you were.

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DECLARATION OF INDEPENDENT WORK

I, Henra Muller, hereby declare that this dissertation, submitted for the degree MAGISTER TECHNOLOGIAE; RADIOGRAPHY (DIAGNOSTIC) in the DEPARTMENT OF CLINICAL SCIENCES, CENTRAL UNIVERSITY OF TECHNOLOGY, FREE STATE, is my own independent work and that it has not been submitted before to any institution by me or anyone else as part of any qualification.

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Signature of student Date

SUMMARY

Over the past two decades, interventional radiology has been a fast developing field with great advances in technology in the diagnosing and treatment of patients. Interventional radiology procedures are minimally invasive and require little to no hospitalisation time. These procedures are fluoroscopically guided and serial runs are used for documentation, so they have the potential to deliver high doses to patients. Reports about deterministic skin reactions resulting from interventional radiology have become more and more prevalent from the early 1990s. Worldwide concern thus led to legislation for the limitation, justification and optimisation of these doses. Setting of diagnostic reference levels (DRLs) for these procedures is difficult, as they can be complex in nature and are often clinically open-ended. In the case where DRLs were used, they needed to be for a specific locality and had to be refined for the specific circumstances. Patients must be informed of the doses they will be receiving during diagnostic or interventional procedures before consent can be obtained from them. Little information on dose audits was available for South Africa at the time of the study, and it was decided to determine dose ranges at a local level.

The research question of this study was: "*What radiation doses do patients receive when undergoing vascular, diagnostic and interventional procedures in the interventional suites at a tertiary training hospital in the Free State?"* The primary objective was to determine the doses and dose ranges to patients. A secondary objective was to identify specific high dose procedures to individual patients and to the population. A third objective was to investigate the factors influencing these doses.

The data of patients who received procedures in two fluoroscopic rooms at the research site were documented over a three-year period. The dose area product (DAP) values were used to calculate skin dose. With the information gathered, dose ranges for frequently performed procedures were determined and specific high dose procedures to individuals and the population identified. Factors influencing the dose were also investigated. This included the relationship of the level of technology, a

patient's BMI and practitioners' level of experience on dose as the research site was a training facility.

The results indicated that both diagnostic and interventional procedures have the potential to deliver high doses, as was evident with the isolated occurrences where the response threshold for deterministic effects was exceeded. Most of the locally performed procedures delivered lower or on par radiation dose, compared to values in the literature. Increased BMI values of patients can negatively influence doses received. The level of a practitioner's experience also plays a vital role in the dose that the patient will receive.

Specific recommendations and the implementing of a dose optimisation protocol are proposed to reduce and optimise doses at the research site. This dose optimisation programme will create greater awareness about radiation dose and effects, follow-up procedures and dose reduction methods amongst role-payers.

Key words: interventional radiology; limitation, justification and optimisation of radiation dose; deterministic effects; radiation dose awareness

PRESENTATIONS ARISING FROM THIS STUDY

AUDIT OF STAFF AND PATIENT DOSES IN A GENERAL VASCULAR LABORATORY (Poster Presentation)	26th South African Association of Physicists in Medicine and Biology (SAAPMB) Congress	6-8 June 2007	Abstract (Appendix I)
PATIENT RADIATION DOSES FOR VASCULAR EXAMINATIONS IN A GENERAL AND INTERVENTIONAL VASCULAR LABORATORY (Paper Presentation)	Faculty of Health Sciences Research Forum University of the Free State (UFS)	23-24 August 2007	Abstract (Appendix I)
HIGHEST DOSE VASCULAR PROCEDURES AT UNIVERSITAS HOSPITAL (Paper Presentation)	Faculty of Health Sciences Research Forum University of the Free State (UFS)	23 August 2012	Abstract (Appendix I)
DOSE DISTRIBUTION FOR VASCULAR PROCEDURES AT UNIVERSITAS HOSPITAL (Paper Presentation)	International Society of Radiographers and Radiological Technologists (ISRRT) 18th World Congress Helsinki, Finland	12-15 June 2014	Abstract (Appendix I)

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LIST OF ABBREVIATIONS AND ACRONYMS

ACR	American College of Radiology
ALARP	As low as reasonably possible
Ba	barium
BMI	Body mass index
BSS	Basic safety standards
$cGy.cm^2$	Centi-gray centimetres squared
CsI	Caesium Iodide
CT	Computerised Tomography
D	Diagnostic
DAP	Dose area product
DRL	Diagnostic reference level
DSA	Digital subtraction angiography
E	Effective dose
ERCP	Endoscopic retrograde cholangiopancreatography
ESD	Entrance skin dose
EVAR	Endoscopic vascular aneurysm repair
FDA	The United States Food and Drug Administration
FOV	Field of view
FPD	Flat panel detectors
FT	Fluoroscopy time
Gy	gray
$Gy.cm^2$	gray centimetres squared
I	Interventional

IAEA	International Atomic Energy Agency
IAP	International Action Plan
ICRP	International Commission on Radiation Protection
ISRRT	International Society of Radiographers and Radiological Technologists
KAP	Kerma-area-product
Ka,r	Reference point air kerma
kV	Kilo-volt
mA	Milli-ampere
mGy	Milli-Gray
mGy.cm²	Milli-Gray centimetres squared
Min	Minutes
MRI	Magnetic resonance imaging
N	Number
NCI	National Cancer Institute
Nd	Not dated
NRPB	National Radiation Protection Board
PACS	Picture Archiving and Communicating System
PSD	Peak skin dose
PTA	Percutaneous trans-luminal angioplasty
PTC	Percutaneous trans-hepatic cholangiography
R^2	Correlation coefficient squared
SAAPMB	South African Association of Physicists in Medicine and Biology
SIR	Society of Interventional Radiology

TBO	Trans-brachial outflow
TFO	Trans-femoral outflow
UAE	Uterine artery embolization
UFS	University of the Free State
UK	United Kingdom
vs	Versus
WHO	World Health Organisation
%ile	Percentile
µGy.m²	Micro-gray metres squared

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CHAPTER 1
LITERATURE REVIEW

1.1 INTRODUCTION

Apart from natural background radiation, medical exposures are by far the largest source of exposure of ionising radiation to the population. Medical exposure contributes more than 95% of the dose that the global population receives from manmade sources (Rehani et al., 2011). Since ionising radiation has enabled great progress in the diagnostic, therapeutic and preventative aspects of medicine, the use of ionising radiation in medicine is justifiable, according to the European Commission (1999). Radiation protection measures to prevent unnecessarily high doses from medical exposure should be taken. Despite the radiation protection measures, there is a global concern among role-players, such as the member states of the International Atomic Energy Agency (IAEA), about ionising radiation dose (dose) in general and the consequences of this dose including biological radiation effects (IAEA, 2010). In this context, an adage that says “You do not know what you are doing unless you know what you are doing” (Giles & Murphy, 2002, p. 875) indicates that one does not know what dose one’s patient receives unless it is monitored.

Little information regarding interventional dose levels audits in South Africa is currently available. The only documented data related to radiation dose audits found at the time of the study were doses to surgeons in theatre (Van der Merwe, 2012), skin doses to patients during fluoroscopically guided back pain management (Acho, Van der Merwe & Van der Merwe, 2009) and a dose audit for fluoroscopically guided procedures such as Ba-enemas (barium) (Nyathi et al., 2009).

The literature search for this research study was done using search engines such as Google Scholar / Chrome / South Africa and Mozilla Firefox, with the following key search words/terms: radiation dose ranges in South Africa / fluoroscopy dose audits / procedures / threshold values / DRLs / deterministic effects. The websites of the

IAEA (http://rpop.iaea.org) and Pubmed (http://www.ncbi.nlm.nih.gov/pubmed) were also used in the search.

The extensive necessary use of radiation in fluoroscopically guided interventions in South Africa begs the question: What are the dose and dose distributions in interventional and diagnostic vascular procedures? It was this question that encouraged the researcher to perform the research study presented in this dissertation. The research question of this study was: "*What radiation doses do patients receive when undergoing vascular, diagnostic and interventional procedures in the interventional suites at a tertiary training hospital in the Free State?"*

1.2 LITERATURE REVIEW INFORMING THE STUDY

The aim of this literature review is to provide background information for this study. A literature overview regarding the biological effects of radiation, the development in the prevention and limitation of these effects, and current issues regarding dose reduction related to interventional radiology will be presented in the following section.

The literature review will inform the reader about the biological effects of radiation, what mechanisms of injury can take place at certain threshold values, what patient doses and mentioned effects were before the 1950's. It will also demonstrate how the development of interventional radiology impacted on these doses and what advantages this field has to the patient. The need for prevention and justification of high doses and associated effects in interventional radiology is paramount which is evident from recent literature. In other words the literature background will demonstrate where we came from, advancements in the field and where we need to be in order to justify and optimise radiation doses at present and in the future.

1.2.1 Biological effects of radiation

On 8 November 1895 Wilhelm Roentgen discovered x-rays, producing the first radiographic images of human anatomy. It was this discovery that led to medical imaging technology (Bushberg et al., 2012) – a process that still uses ionising radiation to produce the image. The physical interaction between radiation and tissue

is that radiation carries enough energy to liberate electrons from atoms or molecules, thereby ionising them (Ionising Radiation, 2013), and this causes chemical effects. When tissues are exposed to x-rays, there is a risk that this radiation can cause these biological effects, such as inflammatory and cell-killing effects, or that it can induce malignancy. The possibility of these biological effects is dose-related and only occurs once a response threshold value has been exceeded. During interventional procedures the relevant threshold value can be exceeded. The International Commission on Radiation Protection (ICRP) states that radiation-induced malignancy can occur even at low doses (ICRP, 2000). The aforementioned mechanisms of the biological effects of radiation injury are examples of radiation effects, namely deterministic and stochastic effects.

Deterministic effects have a threshold of approximately 1 Gy (IAEA, 2010). According to a report of the fourth meeting of the steering panel of the International Action Plan (IAP) for the radiation protection of patients, the risks for deterministic effects on superficial tissues such as the skin or the lens of the eye are higher. The literature consulted on radiation protection indicates that radiation exposure to the skin of individual patients during interventional radiology is known to be greater than for any other radiological procedure. In some interventional procedures, skin doses to patients' approach those used in cancer radiotherapy fractions, and can even exceed 2 Gy (ICRP, 2000). If the dose received is higher than the response threshold causing the effect, the severity of the effect increases as this dose increases. Radiation effects are normally delayed and effects of multiple procedures are additive. These effects will be more severe if procedures are related over a short period of time, e.g. in one week. According to the ICRP (2000), acute radiation doses delivered to tissues during a single procedure or closely spaced procedures may cause: (a) early transient erythema at 2 Gy; (b) main erythema reaction at 6 Gy; (c) temporary epilation at 3 Gy; (d) permanent epilation at 7 Gy; (e) dry desquamation at 14 Gy; (f) moist desquamation at 18 Gy; and (g) delayed skin necrosis at 12 Gy. Depending on the dose received, radiation effects can be visible immediately or after a few days. Delayed effects can occur up to a period of six months after the exposure.

The other mechanism of radiation injury – the stochastic effect – results in an increased risk of radiation-induced cancer and chromosomal effects, with resulting genetic effects in descendants. This effect is regarded as the principal health risk of long-term low-dose radiation. “Stochastic” refers to the likelihood that something will happen. The probability of the effect – for example cancer – occurring, increases with dose, rather than the severity of the effect (IAEA, 2010). The public regards cancer as the primary health effect from radiation exposure. Cancer can be simply explained as uncontrolled growth of cells: “Ordinarily, natural processes control the rate at which cells grow and replace themselves. They also control the body’s processes for repairing or replacing damaged tissue. Damage occurring at cellular or molecular level can disrupt the control processes, permitting the uncontrolled growth of cells - cancer” (Stochastic effect, 2014, http://www.epa.gov).

Ionizing radiation has the power to break chemical bonds in atoms and molecules – it is therefore a potent carcinogen. Another stochastic effect that can take place is changes in DNA – the “blueprints” that ensure cell repair and replacement produces a perfect copy of the original cell (mutations). The body can sometimes fail to repair these mutations or even create mutations during repair. “The mutations can be teratogenic or genetic. Teratogenic mutations are caused by exposure of the foetus in the uterus and affect only the individual who was exposed. Genetic mutations are passed on to offspring” (Stochastic effect, 2014, http://www.epa.gov).

In a special communication of the Image Gently Campaign, Sidhu et al. (2009) state that children are more sensitive to radiation. A child’s lifespan is longer, during which possible changes can occur due to radiation exposure. Even low radiation doses can result in an increased risk of cancer, as demonstrated by using the linear no-threshold model. It is thus necessary to limit the exposure of both children and adults during interventional procedures, as no level of radiation can be regarded as safe.

Since no level of radiation can be considered as risk-free, the above information relates to this study, considering that the research population varied in composition (paediatric to adult) and received a large range of doses.

1.2.2 Patient doses and biological effects during the pre-1950 period

In cases where radiation injuries occurred in the beginning of the 20th century, this was attributed to the primitive imaging devices used after the discovery of x-rays (1895) and ignorance relating to radiation effects. From as early as the 1930s through to the 1950s, fluoroscopy was used during interventional pulmonary tuberculosis procedures. A patient received numerous fluoroscopic studies over an extended period, which resulted in high skin doses with radiation skin damage. These procedures resulted in increased breast doses, which caused breast cancer in many women. This incidence called for radiation dose management and, as a result, regulatory agencies were established to oversee the manufacturing of x-ray equipment. This regulation, as well as the advancements in technology, decreased the incidences of skin injuries caused by fluoroscopy (IAEA, 2010).

The measuring of patients' radiation doses commenced in the 1950s. At that time, it was believed that biological effects caused by ionising radiation were leukaemia and the induction of genetic effects (Wall & Shrimpton, 1998).

1.2.3 Interventional radiology

The present study investigated the doses and dose ranges for vascular procedures that are usually performed as interventional procedures. In this section, interventional procedures relevant to the study are described. Gunther, Vorwerk and Pfannenstie (1995, in Faulkner et al., (nd)) classified interventional radiology procedures as being either diagnostic or therapeutic. Another classification method can be according to anatomical region. Furthermore, it may be subdivided into vascular and non-vascular procedures.

In the report of the fourth meeting of the steering panel of the IAP for the "Radiation Protection of Patients" there are increasing numbers of procedures which use x-rays to guide interventions. These interventions, while replacing a surgical procedure which is desirable from many points of view, include radiation exposure that has the potential for causing radiation injuries. Why perform these procedures if it carries the risk of radiation injury? Korir et al. (2012) claim that when interventional radiology is

compared to conventional surgery, interventional techniques do not require an expensive operating room, space for in-patient hospital admissions and risks associated with the use of general anaesthetics. Interventional radiology allows the biopsy of lesions that had previously been inaccessible via other available means, at a relatively lower cost, but with greater risks of higher dose exposure (Taylor & Rodesch, 1995). However, the question arises as to what exactly these procedures entail. Interventional procedures are defined as procedures comprising guided therapeutic and diagnostic interventions. Percutaneous or other access is used, and they are usually performed under local anaesthesia and/or sedation. Fluoroscopic imaging is used to localise the lesion/treatment site, monitor the procedure, and control and document the therapy (ICRP, 2000). Factors that can influence the duration and complexity of an interventional procedure are the level of difficulty to gain access to a vessel; the tortuosity of the vessel; the level of cooperation from the patient; and whether the patient has multiple pathologies. The impact of the complexity is the increased likelihood of longer exposure time and additional serial runs (Padovani & Peterzol, (nd)).

1.2.4 Deterministic effects and prevention in interventional radiology

From the early 1990s the reporting of radiation induced skin injuries (a deterministic effect) due to interventional procedures started. Interventional procedures are often complicated, and thus they require longer fluoroscopy times than simple diagnostic procedures. Rehani and Srimahachota (2011) estimated in 2011 that 1 680 skin injury occurrences took place per year as a world-wide result from interventional procedures. Other contributing factors to higher skin doses are a lack of awareness, monitoring or understanding of dose limits for radiation effects (Rehani & Srimahachota, 2011). Another concern about interventional procedures is that these procedures are performed more regularly than in the past and their relative numbers are increasing when compared to conventional radiology. These procedures also have the possibility of increased dose, specifically when dealing with complex cases. According to the final report of the IAEA, it was predicted that more complex fluoroscopically guided procedures will be developed and could lead to more procedures that result in radiation injuries. These procedures will not only increase in

number, but it is assumed that they will also be carried out in localities where they will be performed with equipment not designed for dose optimisation (IAEA, 2010).

1.2.5 Documenting and management of dose

The United States Food and Drug Administration (FDA) received reports of noteworthy skin injuries due to interventional procedures in the early 1990s. As a result of these reports, guidance publications were released on documenting radiation use (Stecker et al., 2009). The FDA public health advisory on the avoidance of serious x-ray-induced skin injuries to patients during fluoroscopically guided procedures was released in 1994, and the recording of information that identifies the potential for serious x-ray-induced skin injuries in the patient's medical file was introduced in 1995. In collaboration with professional radiological societies such as the American College of Radiology (ACR), recommendations on patient radiation exposure in medicine were published in 2007. These recommendations were revised in 2008 to specifically include management of the use of radiation in fluoroscopically guided procedures. The guideline topics stipulated the following: (a) patient selection; (b) procedure performance; (c) patient monitoring; (d) appropriate documentation; and (e) follow-up. Stecker et al. (2009) state that it is important to note that interventional radiology procedures are therapeutic of nature and will thus require radiation administration. In other words, radiation may be used in the imaging and treatment process. There is a certain level of associated risk with the use of radiation; this risk is low compared to the benefits that the patient will receive as a result of procedural imaging guidance (Stecker et al., 2009).

Supporting the above statement and showing the way forward, a new radiation exposure rule (Texas Administrative Code rule §289.227) was implemented in the state of Texas, with effect as of 1 May 2013. This rule includes guidelines for radiation reporting, training personnel and establishing dose thresholds. Healthcare providers that perform fluoroscopically guided interventional procedures and Computerised Tomography (CT) must have a radiation programme in place, which entails the following: Patient radiation doses on all CT and fluoroscopy examinations must be recorded, and radiation threshold values for these procedures must be established. Patients must be notified if there has been a dose threshold breach, and

radiation safety training must be provided to all staff performing these procedures. According to a department spokesperson, Christine Mann, the actual doses for each patient need not be calculated, but the exposure parameters should be documented in the patient health record. The radiation dose to the skin will be estimated from the data if necessary (Barnes, 2013).

1.2.6 Justification of high dose procedures during interventional radiology

The use of ionising radiation in medicine is justifiable, since ionising radiation has enabled great progress to be made in the diagnostic, therapeutic and preventative aspects of medicine (European Commission, 1999).

Navarro, Navarro and Maia (2012) declare that interventional radiology is considered the radiological practice that results in the highest exposures of both patients and health professionals, possibly leading to the occurrence of both stochastic and deterministic effects. Although high radiation doses to the skin are delivered during diagnostic and interventional procedures, these procedures have very important advantages. According Navarro et al. (2012) these advantages include the fact that only a small surgical incision is required; the procedures are effective; recovery times compared to post-surgical recovery are reduced; hospitalisation time is decreased, which favours the minimisation of exposure to hospital infections; and costs are reduced.

1.2.7 Setting of reference levels

The ICRP and the IAEA have taken actions to monitor radiation doses and to try to define the amount of radiation dose expected from certain defined procedures. This action may be linked to the current worldwide trend towards defining dose reference levels (DRLs) for various diagnostic procedures, in order to give guidelines to clinicians and radiologists regarding what range of radiation doses could be expected for any particular investigation type (Trueb et al., 2005). DRLs are best defined for each individual centre doing radiological interventions, as disease patterns and equipment vary significantly between centres; thus DRLs will be different for each individual centre (ICRP, 2000). The IAEA (2014) defines DRLs as

dose levels in medical radio-diagnostic practices for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. The International Basic Safety Standards (BSS), which describes standards for good practice, was published in July 2014 by the IAEA. According to a report of the IAP for the radiation protection of patients, there must be great emphasis on the periodic review and appropriate adjustment of reference levels in diagnostic radiology and interventional procedures to optimise the dose (IAEA, 2014).

Optimisation is keeping the dose “as low as reasonably achievable”; taking into consideration economic and social factors such as locality and body type (ICRP, 2007). For diagnostic medical exposures, this optimisation is interpreted as being as low a dose as possible which is consistent with the required image quality necessary for obtaining the desired diagnostic information. In this context of optimisation, DRLs were introduced to act as a reference value and are not to be applied to individual exposures of individual patients. DRLs are particularly useful in those areas where a reduction in individual or collective doses may be achieved or where a reduction in absorbed dose means a relatively high reduction in risk. CT and interventional radiology, which require longer fluoroscopy times, are seen as high dose examinations (ICRP, 2007).

Assessment of patient dose is a relatively straightforward procedure for simple radiographic examinations. In the opinion of Marshall, Chapple, and Kotre (2000) it is less clear whether the DRL concept is applicable to more complex examinations such as interventional radiology procedures. As these examinations become more complicated, and particularly when the outcome is a surgical intervention and not merely a diagnosis, there is likely to be much greater individual variation in the patient doses. Unavoidable complications frequently arise with the positioning of catheters and guide wires, and interventional procedures are usually clinically open-ended, having to continue until the surgery is complete (Marshall, Chapple, & Kotre, 2000). In the present study, the researcher questioned if dose ranges linked to interventional procedures could put patients at risk to develop dose-related injuries or complications.

1.2.8 Current status of protection in interventional studies

The ICRP (1991) has developed principles and concepts regarding radiation protection, namely justification, optimisation and dose limitation. Radiation injuries have been reported in interventional procedures by some of the member states of the IAEA, which alarmed other countries (Rehani et al., 2011). According to the ICRP (2000), radiological procedures should be undertaken only when it is expected that patient management would be positively influenced. To ensure justification, awareness needs to be raised about both the risks and benefits of such procedures among clinicians who request them. To ensure dose optimisation and limitation, all possible steps must be taken to keep the radiation dose as low as reasonably possible (ALARP). Reay, Chapple and Kotre (2003) suggest that the undertaking of interventional procedures may be justified in terms of the benefits the patient, such as longevity and improved quality of life. The radiologist still has a duty of care to ensure that the relatively high exposures are kept as low as reasonably possible, or technically achievable, consistent with a successful clinical outcome.

The IAEA also noted that individual patient doses are increasing for diagnostic examinations and unnecessary or inappropriate examinations are increasingly being requested. In realising this concern the IAEA established an International Action Plan in 2002. The most important aspects of this plan were the development of standardised training material in the form of PowerPoint presentations, guidance documents, a number of publications and a website (http://rpop.iaea.org). This plan led to a series of actions in member states that showed a positive influence on patient radiation protection (Rehani et al., 2011).

According to the ICRP (2000), many patients are not made aware of the risks of radiation injury or followed up to detect the onset of injury, when radiation doses from difficult procedures may lead to such injury. The patient has the right to be informed of the possibilities of such injuries and given the opportunity to decide whether the procedure should be performed – known as informed consent (ICRP, 2000). It is stipulated in the Code of Ethics of the International Society of Radiographers and Radiological Technologists (ISRRT) (ISRRT Version 07062010/ppr) that “patients/clients/relatives [must be] provided with the necessary information,

including radiation dose, to enable them to make informed decisions about their examinations and treatment, encouraging their full participation in treatment decisions and goals" (http://www.isrrt.org).

The ideal situation is that patients should be informed of these risks when they will be exposed to an interventional procedure associated with a high radiation dose that carries a significant risk of a radiation injury. Furthermore, patients need to be counselled by the radiologist after the procedure on the radiation dose received, as well as the possible radiation risks. In order to obtain informed consent from and explain possible risks to a patient, it is necessary to consider and present to the patient the anticipated dose from the interventional procedures. It would be necessary to discuss the two additional radiation risks during patient imaging and/or treatment, namely deterministic and stochastic effects. It is therefore important to identify those procedures with a risk of radiation injury in order to facilitate informed consent.

The Bonn Call-for-Action was a specific outcome during the "International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade" held in Bonn, Germany, December 2012 by the IAEA. This was a joint Position Statement of the IAEA and World Health Organisation (WHO) released earlier in 2013. "The aims of the Bonn Call-for-Action are to: a) strengthen the radiation protection of patients and health workers overall; b) attain the highest benefit with the least possible risk to all patients by the safe and appropriate use of ionising radiation in medicine; c) aid the full integration of radiation protection into health care systems; d) help improve the benefit/risk-dialogue with patients and the public; and e) enhance the safety and quality of radiological procedures in medicine" (http://rpop.iaea.org).

1.2.9 Patient dose management

The Society of Interventional Radiology (SIR) released "Guidelines for Patient Radiation Dose Management" (Stecker et al., 2009), to be used for radiation dose management linked with interventional radiological procedures. A summarised version of a combination of the work of Stecker et al. (2009) and Vañó et al. (2013) is

given below, i.e. pre-procedural planning; intra-procedural management and post procedural care are outlined in the following section.

1.2.10 Pre-procedural planning

Individual training: The radiographer is responsible for being knowledgeable about dose levels. Initial training needs to take place in patient radiation management for all personnel working in the interventional radiology suite (e.g. nurses and radiographers). Refresher training in radiation management (institutional policies and government regulations) must be repeated annually.

Informed consent: A patient or, in the case of a minor, the parents or legal guardian, should be informed of possible radiation risks, especially if the expected radiation dose is high. Clear and unambiguous language is to be included in the consent form, and “it is more than just a signed document, it is an active process between the physician and patient” (Stecker et al., 2009, p. 268). Previous radiation exposure should be taken into account during the planning process of the procedure.

Procedure planning: All pre-procedure imaging and, if possible, these images, must be reviewed instead of reviewing reports only. These images may help in reducing procedure time; reducing fluoroscopy time and the amount of fluoroscopic images needed, and lowering the overall complication rates of the specific procedure. Non-invasive cross-sectional imaging modalities (such as magnetic resonance imaging (MRI) and ultrasonography) can be used as part of the planning process regarding access routes and device choices.

Patient’s BMI (body mass index): Weigh and measure all able patients for diagnostic interventional procedures to determine their BMI value. This step will indicate of how complex the procedure might be. It has also been shown that increased patient BMI values result in increased patient doses (IAEA, 2010).

1.2.11 Intra-procedural management

Procedural radiation monitoring: The onus for dose monitoring during the procedure normally falls on the radiographer (technologist). Table 1.1 will assist the radiographer with dose monitoring during procedures.

Table 1.1 Summary of radiation monitoring dose notification thresholds (Stecker et al., 2009, p. 269)

Parameter	**First notification**	**Subsequent notifications**
Peak skin dose (PSD)	2 000 mGy	500 mGy
Reference point air kerma (Ka,r)	3 000 mGy	1 000 mGy
Kerma-area-product (PKA)	300 Gy.cm²*	100 Gy.cm²
Fluoroscopy time (FT)	30 min	15 min
*Assuming a 100 cm² field at the patient's skin. The value should be adjusted to the actual procedural field size.		

mGy=milli-Gray; Gy.cm²=Gray centimetres squared; min=minutes; cm²=centimetres squared

The intention of this table is to enable the radiographer to assist the practitioner, performing the procedure, in monitoring of the radiation dose throughout the procedure. The radiographer will notify the practitioner when the peak skin dose ''reaches 2 000 mGy, then every 500 mGy after that". The radiographer will notify the practitioner of the ''reference point air kerma initially at 3 000 mGy and then every 1 000 mGy thereafter''. In the case that a unit can only monitor fluoroscopy time, the practitioner will be notified when the ''total fluoroscopy time has reached 30 minutes and then in increments of 15 minutes or less'' (Stecker et al., 2009, p. 269).

There are varied viewpoints available in the literature on threshold values and what dose measure should be used to evaluate deterministic risk. The widely accepted threshold value for transient erythema is 2 Gy (ICRP, 2000) and although individual sensitivities of patients can vary, Waite and Fitzgerald suggested as early as 2001 that entrance skin doses (ESD) greater than 1Gy should be recorded. According to the IAEA (2007) the air-kerma-product is a more accurate indicator of risk than ESD, as air-kerma-product is a product of entrance skin dose and field size. In the study of

Urairat et al. (2011) the displayed air-kerma-product was converted and used to determine a concerned level of deterministic risk of 2 Gy. The Urairat et al. (2011) study's resultant correlation factors (R^2) between deterministic risk and air-kerma-products ranged from 0.69 to 0.98. The authors concluded that the air-kerma-product meter can be utilised as a monitoring tool for early transient erythema or epilation. Rehani and Srimahachota (2011, p. 9), on the other hand, discourage compliance to any dose effect table and state that "doses are not rigid boundaries". Skin dosimetry is not likely to have accuracies of more than ±50%. The National Cancer Institute (NCI) suggested bands of doses for single site acute skin dose and skin reaction grade: "A1 (0-2 Gy) no Grade; A2 (2-5 Gy) Grade 1; B (5-10 Gy) Grade 1-2 C (10-15 Gy) Grades 2-3 and D (.15 Gy) Grades 3-4'' (Rehani & Srimahachota 2011, p. 9).

The interventionist performing the procedure should take into consideration the radiation dose that the patient has already received as well as the dose needed to complete the procedure. Keeping the risk-benefit ratio for the patient in mind at all times (although it is unlikely that a procedure will solely be stopped for breaching radiation thresholds), the dose of any additional procedures in the following 60 days should be monitored closely. The dose of subsequent procedures will be added to the dose that has already been received. Bi-plane units' doses should be evaluated individually if the fields do not overlap, but should be added if they do.

Dose minimisation techniques: Vañó et al. (2013) suggest a dose optimising programme as follows:

Always use the lowest pulse rate fluoroscopy mode where possible. The low dose rate selected still needs to deliver adequate images for diagnostic purposes. Limit the fluoroscopy time and limit the number of digital subtraction angiography (DSA) frames and runs to the minimum, while "still achieving the clinical goals of the procedure" (Stecker et al., 2009, p. 269). If selecting high frame rates, this needs to be justified for procedures with high-flow dynamics (Kloeckner et al., 2012). Use the "frame grab" option whenever possible for some of the fluoroscopy images, and store fluoroscopic scenes (films) for documentation. Pitton et al. (2012) claim that only 30% of the total DAPs are a result fluoroscopy, while the other 70%, is from DSA frame series typically used for documenting the procedure. The total radiation

dose may be substantially lowered by storing fluoroscopic scenes rather than performing DSA frames. Collimate to the area of interest using virtual collimation. Keep the image detector as close to patients as possible and the x-ray tube as far as possible from the patient's skin. This gap can be minimised by elevating the table (Pitton et al., 2012). Use magnification options sparingly. The zoom function should be used only if clinically essential. "C-arm angles should be varied from time to time if this does not interfere with the conduct of the clinical procedure, in order to minimise skin dose" (Stecker et al., 2009, p. 269).

1.2.12 Post procedural care

As part of a quality control programme, interventional radiology units must evaluate and record patient radiation doses. Criteria must be set to include patients for follow-up when dosimetric limits have been exceeded.

Dose documentation: Record all patient and procedure data correctly to ensure accurate information, which can be used for dose calculation purposes. Evaluate and analyse patients' DAP values. This evaluation must be done immediately after completion of the procedure for all procedures involving fluoroscopy. Determine whether the patient will require a follow-up and inform the radiologist. The radiologist will schedule a follow-up with the patient's referring clinician. This documentation allows for transparency and inspires confidence, especially to the patient and referring clinician (Kloeckner et al., 2012).

The guidelines stipulated by the SIR must be followed in the dose-recording process. The peak skin dose and kerma-air-product must be recorded, as this acts as an indicator for biological effects. Comparing a patient's dose to the table from the SIR guidelines will help in determining if a patient requires follow-up. "These values are meant to trigger a follow-up for a dose that may result in a minor reaction in an average patient" (Stecker et al., 2009, p. 270). If the patient's peak skin dose reaches 2 000 mGy, kerma-air-product exceeds 500 Gy.cm² or the fluoroscopy time exceeds 60 minutes it indicates a follow-up is required. Fluoroscopic time alone is not a good indicator of dose received, but can be indicative of a significant radiation dose.

Patient follow-up: All patients who received dose values that reached the threshold value for deterministic effects are to be followed up. This does not imply that dose values beneath the threshold values are safe, but it is probable that doses higher than the threshold value will cause radiation injuries. Follow-up is recommended even if the dose values were lower, but the same anatomical site received radiation recently. A patient who has received a noteworthy amount of radiation will be given clear instructions for self-examination of the irradiated area. If skin changes have occurred, the patient will have to inform the physician who performed the procedure or the referring doctor. A medical physicist will evaluate the dosimetric aspects.

1.2.13 Dose and image quality assessment

A periodical statistical report of dose recording and dose utilisation is required. All procedures that have reached or exceeded the threshold values should be reported to the radiation control officer. Annual assessment of image quality versus radiation dose must form part of a complete quality control programme by an in-house medical physicist.

1.2.14 Remaining challenges in interventional radiology

According to Wall (2001), hospitals performing high numbers of angiographic and/or interventional procedures should develop DRLs for the more common interventional procedures, as the distribution and complexity is dependent on individual circumstances. During this study, a wide distribution (ethnic composition) of patients was observed; it was said that these values (DRLs) should be specific to a country/region. What this means is that a centre cannot adopt prescribed DRLs of another centre as is, and that a certain level of refining of these values has to take place to make it applicable for their unique circumstances and patient specifics.

In the South African context, as mentioned, a study was done at the Charlotte Maxeke Johannesburg Academic Hospital, during the period August 2007 to March 2008. This retrospective study was aimed at dose optimisation for fluoroscopic procedures, radiation doses delivered to patients undergoing fluoroscopy examinations in terms of the skin dose, and the dose-area product (DAP). These

procedures included fluoroscopy examinations such as Ba-enemas, only (Nyathi et al., 2009).

Most fluoroscopic equipment delivers “surrogate measures” for skin dose only (Dauer et al., 2009). A prescribed methodology for evaluating skin doses to patients during interventional procedures is crucial. It is also suggested that trigger levels requiring clinical follow-up be developed. In a recent study by Jones, Ensor and Pasciak (2014), the accuracy of calculating the peak skin dose (PSD) from indirect metrics such as reference air kerma / kerma-area-product (KAP) and direct measure of radio chromatic film is compared. Before this displayed reference air kerma can be used to calculate a surrogate measure for skin dose, the accuracy of this value should be verified. It was found that PSD could be determined from indirect measures with a better than 50% accuracy for vascular and interventional oncology procedures. These calculated PSD values can be used to determine if follow-up is required if the set trigger level has been reached or exceeded (Jones, Ensor & Pasciak, 2014).

DAP values of patients undergoing fluoroscopic diagnostic or interventional procedures at the research site were measured and documented as prescribed in the literature. Routine calculations of skin dose determined from DAP values and field area was not part of the current practice at the research site. Regular dose audits and routine follow-up did not take place at the research site, at the time of the study, as is recommended and stipulated in the literature.

1.3 CONCLUSION

Interventional radiology is regarded as procedures that can result in high skin doses because of their complex nature and duration. These high skin doses could result in skin injuries (deterministic effects). It is important that referring clinicians, radiologists, radiographers and patients are aware of these potentially high doses. Patients receiving such doses should be informed and counselled about possible radiation effects in order to avoiding unnecessary radiation phobias. Routine follow-up should be done if patients exceed response threshold values for deterministic effects. In optimising known high dose procedures, deterministic effects will be

avoided in individual patients undergoing justified but long, complex procedures (Wall, 2001).

In this chapter, the background for the study was provided with reference to the literature review. The results and recommendations of this study will be of value to fill the gap in the shortcomings of the current information in South Africa relating to dose and dose ranges for interventional procedures, even if only at local level. In the next chapter the motivation for this study, research objectives, design and the methodology to address the research question are described.

CHAPTER 2
OVERVIEW OF THE STUDY AND RESEARCH METHODOLOGY

2.1 INTRODUCTION

The purpose of this chapter is to describe the motivation, research question and methodology for this study to determine radiation doses to patients during diagnostic and interventional procedures. The research design, research site details, population sample size and the method for documenting the data are discussed. The steps that were taken in order to present valid and reliable research findings, the method of grouping of data, as well as the analyses performed are outlined.

2.2 PILOT STUDY

During 2007, a retrospective study with the title “Audit of Staff and Patient Doses in a General Vascular Laboratory” was carried out in conjunction with the Department of Medical Physics, for the period 1 February 2006 to 31 January 2007. The following data were recorded: a) date of the examination; b) patient’s unique identifier; c) procedure; d) DAP value; and e) screening time. A total of 1 150 diagnostic and interventional procedures were recorded. The findings of this study were presented at the 26th South African Association of Physicists in Medicine and Biology (SAAPMB) Congress in 2007 and showed that some of the procedures included in the study exceeded the response threshold value for deterministic effects of 2 000 mGy, namely uterine artery embolization (UAE) and endoscopic vascular aneurysm repair (EVAR) (Appendix A).

The results of the pilot study warranted further research, as some procedures exceeded the response threshold value of 2 000 mGy.

2.3 MOTIVATION

It is evident from the literature review that careful attention to the radiation dose to patients is needed during interventional procedures. Although the DAP values of patients were documented at the research site, doses were not calculated. Dose optimisation could only be initiated once these doses were known.

The research site is a tertiary training hospital in central South Africa. In the diagnostic radiology department interventionists, consultant radiologists and registrar radiologists perform vascular procedures in two separate suites, namely the vascular suite and E-room. A large range of diagnostic and interventional radiology procedures are carried out in these vascular suites. This range includes diagnostic angiographic procedures, vascular interventional procedures and nonvascular interventional procedures. These procedures are done on most organ systems, including the brain, kidneys, lungs and extremities. The procedures vary significantly in duration (referring to fluoroscopic time in seconds) depending on their variable complexity.

As is evident from the literature, it is rather difficult to establish specific DRLs for interventional procedures due to the complexity and variability of the procedures (European Commission, 1999). Although DAP values were documented, the calculation of dose values (Gy) for vascular procedures at the research site had not been part of departmental procedure in the past. Dose values are often easier to interpret as it takes the field area into consideration, and threshold values for radiation effects are expressed in Gy. The ideal situation is that patients need to be counselled on the radiation dose received, as well as the possible radiation risk.

At the research site it had not been current practice to inform patients about the radiation dose or risks associated with the interventional procedures. Research was needed to determine the doses at local level.

2.4 RESEARCH QUESTION AND OBJECTIVES OF THE STUDY

The research question of this study as previously stated was: "*What radiation doses do patients receive when undergoing vascular, diagnostic and interventional procedures in the interventional suites at a tertiary training hospital in the Free State?"*

The primary objective of the study arising from this question was to determine the doses and dose ranges to patients. A secondary objective was to identify specific high dose procedures to individual patients and the population. A third objective was to investigate the factors influencing these doses. In addressing the objectives, these various aspects will be examined in subsequent separate chapters.

In this study, DAP values and dose values (Gy) were found to be more achievable measures than determining DRLs, to be used to assess the radiation dose to the patients. It has been decided that determining DRLs would not be practical due to the large variation in duration of interventional procedures. The fact that the research site is a training facility means that the radiologists/interventionists performing these procedures have various levels of experience. DRLs must be specific to a country or a region (Wall & Shrimpton, 2001) and dose distribution and identifying high dose procedures to individuals and the population would be invaluable to the research site.

2.4.1 Dose ranges for all diagnostic and interventional procedures

The dose ranges determined provided the patients' background information about the radiation dose they would expect to receive during the specific procedure. As already stated, informed patient consent is an essential component of medical practice; hence, counselling the patient (or the guardian in the case of a child) on the risk of a procedure is mandatory (ICRP, 2000). With this information available, the patient will be enabled to give meaningful informed consent for the procedure as they will be able to understand the risks of suffering possible radiation injuries which may occur in extreme cases.

The dose ranges determined will also serve as guidelines to radiologists, clinicians and radiographers at the radiology department of the hospital. These dose ranges will inform the professionals about the range of radiation doses that could be expected for any particular diagnostic or interventional investigation type. The referring clinician will be able to assess the advantages and disadvantages (or risks) of the procedure, considering the patient's clinical history. This information will also allow both the radiologist and clinician to make informed decisions about the treatment if radiation effects were to occur, as well as the aftercare of the patient after a particular procedure. Based on the dose ranges determined by this study and presented in Chapter 3, the radiologist will be more aware of the probable incidence of skin injuries and/or risks of radiation-induced cancer, should the procedure be repeated. According to the ICRP (2000) there is a probability of inflammatory and cell-killing effects, including skin desquamation and ulcers. These effects are dose-related: once the dose exceeds a significant threshold (2 Gy), skin injuries can occur and younger patients may face an increased risk of future cancer. The threshold dose for the skin is relatively high (2 Gy), but can easily be exceeded in some interventional procedures (ICRP, 2000).

2.4.2 Identify specific high dose procedures which may require patient follow-up to monitor skin effects

Mild skin injuries might go unnoticed if patients who received more than 2 Gy to the skin are not followed up (IAEA, 2010). Measures to decrease radiation doses and to limit radiation effects must be taken, especially for the identified procedures. Procedures that may require alteration of and/or recommendations to specific procedures that will require patient follow-up have been identified. The optimisation of patient doses will help identify procedures in most urgent need of further investigation and corrective action (Wall, 2001). Radiation effects are normally delayed and effects of multiple procedures are additive. These effects will be more severe if procedures are carried out over a short period of time, e.g. in one week.

Dauer et al. (2011) indicate that although the highest radiation dose is to the skin at the entrance site of the radiation beam, other organs receive varying radiation doses from either the direct x-ray beam or scattered radiation. Organ doses are determined

by the Effective dose (E), introduced by the ICRP (2007), which is the tissue weighted sum of the equivalent doses in all specified tissues and organs of the body. Although E has widely been used as a stochastic risk surrogate, this tissue weighted factor was not used in this study as it is sometimes wrongly used to demonstrate exceeding of threshold values of specific organs. Effective dose has been described as “not useful for estimating potential for skin injury” (Rehani & Srimahachota, 2011, p. 9). According to the final report on Dose Optimisation in Fluoroscopically Guided Interventional Procedures, most radiation induced injuries can be prevented and doses to patients for these procedures can be lowered and optimised (IAEA, 2010). A comparison was done of how radiation doses calculated as part of the study relate to threshold values for radiation effects. The details are presented in Chapter 3.

2.4.3 Comparison of doses for similar procedures performed in the two different venues, namely the vascular suite and E-room (newer technology)

Over time, radiation output and image quality of fluoroscopic equipment can change. Aging image intensifiers can cause fading image quality and are sometimes compensated for by increased dose delivery (IAEA, 2010). The radiation dose of the vascular suite and E-room was evaluated. In Chapter 4 a comparison is drawn between the similar procedures that were performed in the two fluoroscopic rooms.

2.4.4 Correlation of the BMI value of the patient relates to the dose received

Body mass index is the mass of an individual in kilograms divided by the square of the individual’s height in metres (kg/m^2). Fluoroscopic dose rates are influenced by a patient’s body mass, as the dose output increases with increasing beam attenuation due to increased patient mass (IAEA, 2010).

For Chapter 4, the BMI values available for patients who had been weighed and measured during a six month period were used to investigate how this factor relates to the dose received.

2.4.5 The relationship of the practitioner's experience to the skin dose received

According to the final report on Dose Optimisation in Fluoroscopically Guided Interventional Procedures (IAEA, 2010), the experience of interventionists is a major factor in dose management. It has been shown that even under well-monitored and controlled training conditions; there have been significant increases in the dose to the patient delivered by interventionists who are less skilled.

The level of the practitioner's experience and training has been used to classify them into three standard groups, or classes, as follows: interventionist, consultant and registrar (Table 5.1). The radiation dose delivered by these groups was evaluated and compared for similar procedures presented in Chapter 5.

2.5 RESEARCH DESIGN

This research study, conducted at the vascular suites of the department of diagnostic radiology at a tertiary hospital in the Free State was a quantitative, cross-sectional study. According to Katzenellenbogen, Joubert and Abdool Karim (1997), this type of study is usually done in assessing exposure-outcome relationships. Cross-sectional implies that the study involved the analysis of data collected from a population, at one specific point in time and aimed to provide data on the entire population included in the study. The scientific nature of the research study required quantitative research. A large amount of data was gathered and then analysed statistically. This allowed for very little bias. A disadvantage in quantitative research that needs to be noted is that researchers are trying to answer their hypothesis and can bias how they look at the results and which parts of the results are presented. Quantitative research is reproducible, if other researchers ran the analysis on the data they would always end up with similar results. The researcher also had more control over how the data was gathered. Both retrospective and prospective data capturing for patients undergoing vascular procedures at the vascular laboratories were performed. Ethical approval was obtained in May 2007; thus, for the inclusion period of 1 February 2006 to 31 January 2009, most of the data had been captured retrospectively, with some data captured prospectively.

2.6 INFRASTRUCTURE

2.6.1 Research Site

The research site is a tertiary state hospital with a public-private partnership and 670-bed capacity. The study was conducted at the vascular suites of the department of diagnostic radiology in the Free State. The procedures in the vascular suite were performed using a Siemens Multistar 180° Multispace Swivel, and a Siemens AXIOM Artis with its flat panel detector was used in E-room. Both were single-plane x-ray systems. A Diamentor DAP meter (PTW, Freiburg, Germany) fitted to the under-couch tube assembly was used to monitor patient doses in both rooms.

2.7 RESEARCH POPULATION

The target population of this study included patients who had undergone diagnostic and interventional vascular procedures that involved fluoroscopic x-ray exposure at either of the two vascular suites at the research site. This population ranged from new-born to geriatric patients, males and females from all ethnic groups. Similar to the methodology in a study conducted by Dauer et al. (2009), it must be emphasised that there was non-randomised allocation of patients to the doctors performing these procedures. There was no attempt to influence how a procedure was performed in respect of factors such as fluoroscopic technique and image acquisition. Thus, the results of this study are representative of the practice at the time of diagnostic and interventional procedures at the research site. A total of 3 310 patients' data were captured in the database over the three-year period, of which 230 were excluded from the study due to missing or incomplete data.

2.7.1 Sample size

This study's sample size consisted of all patients who had undergone any of the above procedures at either of the vascular suites at the research site during the inclusion period of 1 February 2006 to 31 January 2009. Table 2.1 lists the inclusion and exclusion criteria for patients during this study.

Table 2.1 Criteria for patients included and excluded in the study

Inclusion criteria	Exclusion criteria
Patients undergoing vascular procedures involving fluoroscopic x-ray exposure at the vascular suites at the research site.	Patients undergoing non-vascular procedures, such as ultrasound guided biopsies.
Procedures included screening and/or exposure due to single shot images or exposure series.	Patients who received no x-ray exposure during the procedure.
Patients undergoing diagnostic and/or interventional procedures	Patients for which no DAP meter reading was available due to user omission or technical difficulties (such as during a power failure).

2.8 DATA SHEET

Patient data (doses) for the three-year period for all patients undergoing a vascular procedure in the vascular suite and E-room were entered in a database. The database was designed to capture both DAP and screening times for the various procedures, both diagnostic and interventional. Data for all the required fields were collected from the patient procedure record books.

A data sheet (spreadsheet) was designed in collaboration with the Department of Biostatistics; University of the Free State, to capture the information required in Microsoft Office Excel 2007 for the pilot study. The data sheet was subsequently revised after the pilot study. The additional information required was the patient's unique identifier to the hospital; the type of the procedure; the doctor and their class group; E-room's data; and the height and weight of patients during a six-month period. The advantage of capturing the unique identifier "UM number" was that it provided the opportunity to revisit the patient information for follow-up purposes. For dose distribution to be calculated, procedures were grouped as being either diagnostic or interventional (Appendix C). An error field was added to indicate the number of patients/procedures for which no DAP reading was found.

2.8.1 Documenting data

The information was entered on the data sheet using the headings as shown in Appendix B. A numerical field was assigned to each procedure and only the number of the corresponding procedure was captured in the spreadsheet, e.g. 1-76 (Appendix C). Data were collected retrospectively from 1 February 2006 to 22 May 2007 and prospectively from 22 May 2007 to 31 January 2009. For the period 1 February 2006 to 31 December 2007, the DAP meter readings in the vascular suite had to be printed at the end of each procedure and the meter reset to zero, as the meter was located in a separate room. It happened that at the end of some procedures, a slip was not printed and the DAP meter was not reset between patients. Those patients' data had to be omitted. For the remaining period of 1 January 2008 to 31 January 2009, the two DAP meter readings and screening times were documented by the radiographer in the procedure book, as the DAP meter was no longer used. The readings were displayed on a computer monitor upon completion of the procedure. In E-room, patients' DAP meter reading and screening times were documented in a procedure book. This was also displayed on a computer monitor upon completion of the procedure.

The aim was to analyse procedures with more than 30 entries. Procedures with less than 30 entries were omitted from the individual evaluation, because these data represent less than 1% of the total number of patients in the study.

Data are presented as tables and graphs to represent the mean and maximum doses received (Chapter 3, section 3.3). The dose values are expressed in the SI unit mGy. The results are displayed in tables for diagnostic and interventional procedures, where some procedures were grouped as previously stated. The highest dose diagnostic and interventional procedures to individual patients are shown, as well as the highest dose diagnostic and interventional procedures to the population.

2.9 DATA VALIDATION

In order to present valid and reliable research findings as part of this quantitative research design, measures have been developed to ensure valid and reliable

research findings. The reliability refers to the consistency of a measure, while validity refers to the extent to which a questionnaire/test measures what it purports to measure (Muller, 2014).

The regular medical physics quality assurance programme at the research site ensured that the DAP meter readings documented were valid and reliable, which included calibration of the DAP meter. As a further measure to ensure that the data were correctly entered, the researcher scrutinised the data. If the data did not follow anticipated trends, the researcher referred back to the patient records to verify and, if necessary, correct any suspicious data. Procedures were also given a number, which was then classified as either being a diagnostic or interventional procedure. A given number could be only diagnostic or interventional, not both. The above method for procedures was used as a corrective measure, verifying the data after it had been entered. Both Microsoft Office Excel 2007 and Microsoft Office Access 2007 were used to track and rectify incomplete data.

2.10 ANALYSIS OF DATA

Data were grouped according to examination type. Procedures were grouped before and during data analysis. To confirm the grouping, histograms for each individual procedure in a group were drawn (Figures 3.1-3.3). Based on the shape of the distribution of the histograms, individual procedures could be grouped as follows:

The Arterial Outflow Group included trans-femoral outflow (TFO), arch of the aorta (aorta grams) and trans-brachial outflow (TBO) procedures. These diagnostic procedures are considered as similar procedures, as all measure similar functional parameters; the only difference is the entry site of the catheter. The access site for TFO and arch of the aorta is through the femoral artery and for TBO through the brachial artery.

The Cerebral Angiogram Group included four-vessel angiogram and six-vessel angiogram procedures, both of which demonstrate major cerebral arteries; additionally, a six-vessel angiogram demonstrates the internal carotid artery uni-/bilaterally.

The Embolization Group included all different types of embolization, differing by the anatomical site where the embolization is performed. The general access site would be through the femoral artery.

For both grouped and ungrouped procedures, skin dose values in mGy were calculated taking the area (cm^2) of exposed skin surface from DAP meter readings in $cGy.cm^2$ of each procedure into account. “If field area in cm^2 is known for a particular exposure (e.g. at the skin surface), then the incident accumulated air kerma in mGy at that point can be calculated by simply dividing the KAP measurement by the area” (Bushberg et al., 2012, p. 306). The following equation was used to calculate dose for a procedure: Dose = DAP value ($cGy.cm^2$) / area (cm^2). The result in cGy then has to be multiplied by 10 to give the dose value in mGy. An estimated 10% error may occur in the field area average field dimensions. For this study, standard field sizes were used per procedure (Appendix C) for the purpose of uniformity. As a result of this error, the results after the dose was calculated (mGy) were rounded to the nearest whole number.

The 10 procedures that contributed the highest (maximum) dose to an individual patient were identified. The 10 procedures that delivered the highest collective dose to the population were also identified. A comparison was made between doses received from diagnostic and interventional vascular procedures. Dose distributions for each examination type were calculated from the data collected over the three-year period. Each individual procedure was evaluated, but similar procedures were also grouped and evaluated. The derived statistics were confidence intervals for different procedures, percentiles and average values. These distributions were compared with documented international values according to the ICRP (2000).

2.11 ETHICAL APPROVAL

Ethical approval for the pilot study done during 2007 was obtained and granted for a period of three years commencing 22 May 2007 (ETOVS NR 66/07) (Appendix D). An extension of the ethical approval was requested and obtained for the current study, as this proved to be more extensive than the pilot study. The head of clinical

services of this hospital also granted permission for the study to be performed (Appendix E), as well as the Radiation Control Committee (Appendix F).

The research project did not involve any additional cost to the patient nor additional radiation exposure. All patients signed a consent form for the procedure to be carried out. Patients who were weighed and measured signed an additional consent form, giving permission for this anonymous data to be used in this study (Appendix G).

2.12 SIGNIFICANCE OF THE STUDY

Even though interventional radiology is a fast growing field with complex fluoroscopically guided procedures that involve long fluoroscopy times and sometimes multiple runs of serial imaging, some interventionists do not acknowledge that skin injuries as a result of the high radiation dose received have and could occur. The incidence of radiation skin injuries will increase unless the causes for these high doses are identified and restricted (IAEA, 2010).

It was thus the aim to use the results of the study to determine dose ranges at the research site for diagnostic and interventional procedures. Specific high dose procedures to individual patients and the population, that may require follow-up, will be identified. Factors that can influence the dose to the patient in our environment will be evaluated. The information (dose ranges, high dose procedures and the factors influencing these doses from this study will result in better informed clinicians, interventionists, radiographers and patients as the

2.13 CONCLUSION

This chapter presented an outline for the study, the research question, objectives and research methodology to address the research question, namely what radiation doses patients receive when undergoing vascular, diagnostic and interventional procedures in the interventional suites at a tertiary training hospital in the Free State. A quantitative cross-sectional study was done, which included retrospective and prospective data capturing for patients undergoing vascular procedures between 1 February 2006 and 31 January 2009. In the next chapter, the determination of

dose ranges for diagnostic and interventional vascular procedures, as well as the identification of specific high dose procedures, will be examined and discussed.

CHAPTER 3
DOSE DISTRIBUTION FINDINGS FOR DIAGNOSTIC AND INTERVENTIONAL PROCEDURES

3.1 INTRODUCTION

Interventional radiology procedures are known to deliver high skin doses due to their complex nature and long duration; consequently, dose audits of these procedures are of undeniable benefit (McParland, 1998). The dose associated with these procedures may result in possible skin injuries; it is thus important for referring clinicians, radiologists, radiographers and patients to be aware of these potentially high doses and long imaging times. This is becoming more important as interventional procedures are performed more frequently each year (Bor et al., 2008). At the research site there was an increase of 10.6% in the number of interventional procedures being performed from the first to the second year, and a 4.3% increase from the second to the third year of the study period.

To place interventional procedures for this study into perspective, it is important to indicate the differences between diagnostic and interventional vascular procedures. The SIR released a global statement in 2010 regarding the importance of Interventional Radiology (IR) in medical care for patients, which identifies and explains the scope of IR worldwide (Global Statement, 2014). Diagnostic vascular procedures involve the interpretation of medical images to identify injury and disease using x-ray fluoroscopy. Examples of these procedures are cerebral angiography and arterial outflow studies. Interventional vascular procedures are nonsurgical treatments for a number of medical conditions – most commonly for vascular diseases or abnormalities. Examples of these treatments include angioplasty, thrombolysis, endarterectomy, embolization of bleeding vessels and occlusion of brain aneurysms. Interventional radiologists can perform these procedures under the

guidance of x-rays, magnetic resonance or other imaging methods, depending on the available technology.

At the study site, these interventional procedures or treatments are performed with x-ray fluoroscopic imaging. Because the above mentioned procedures involve a radiation dose to the patient, it is important to be aware of the dose received by the patient during these procedures. As some of these procedures can deliver high skin doses, it is of value to identify those procedures that may carry a risk of radiation injury. If personnel members were to be informed about the radiation doses associated with interventional procedures and took note of the potential radiation injuries that are associated with procedures beyond the threshold dose values, they would be able to answer specific questions or concerns raised by the patient. Personnel members would also be more aware of dose optimisation by making use of different techniques of radiation protection during these high dose procedures. If a patient is knowledgeable about the radiation dose received and the possibility of radiation injuries they might incur, they would be able to seek help sooner if, for example, skin changes were to occur.

The primary objective of the study was to determine from the patient records the dose distribution (dose ranges) for specific diagnostic and interventional procedure types carried out at the vascular laboratories of a tertiary hospital in the Free State. DAP values were used as dose measure (See Chapter 2, section 2.3). A secondary objective of the study was to identify specific high dose procedures to individual patients and to the population.

3.2 METHODOLOGY FOR DETERMINING DOSE RANGES

Data were captured of patients undergoing diagnostic and interventional procedures which involved fluoroscopic x-ray exposure at either of the two vascular suites (vascular suite or E-room) at the research site during the inclusion period of 1 February 2006 to 31 January 2009. The methodology used is discussed in Chapter 2. Data analysis was done by determining average values, confidence intervals and percentile values for procedures.

Individual procedures were grouped so as to achieve more representative sample sizes during data acquisition and during data analysis. For verification of the groupings, histograms for individual procedures in a group were created, with the exception of the embolization group. Based on the shape of the distribution of the histograms, individual procedures could be grouped as described in Chapter 3 (Figures 3.1-3.3).

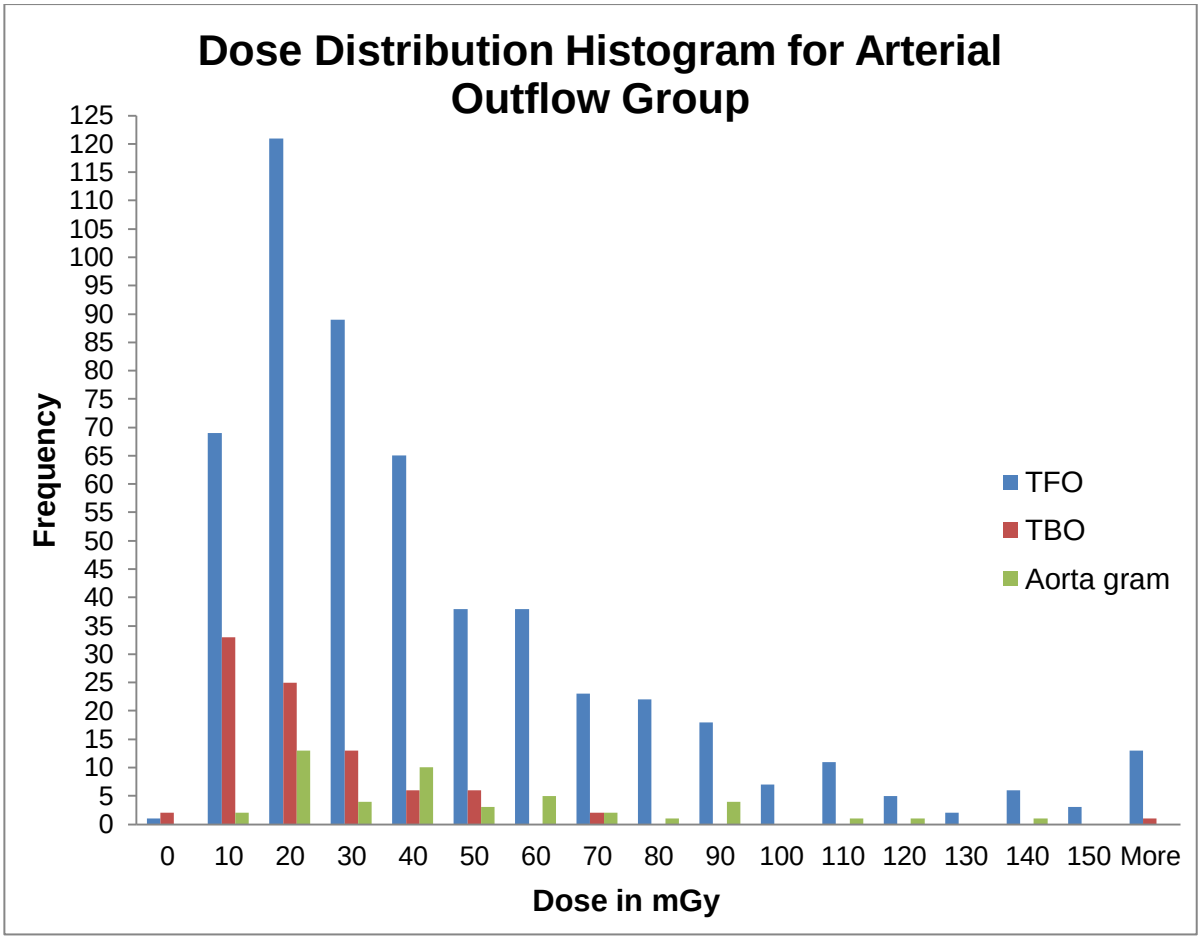
3.3 DOSE RANGES OBTAINED FOR DIAGNOSTIC AND INTERVENTIONAL PROCEDURES

A total of 3 310 patients' data were captured, 230 of which were excluded from analysis (see Chapter 2, section 2.7). The number of procedures (n values) of the tables may be less than this initial value, as only procedures which had 30 or more entries are reflected.

The sequence of data presented will be:

- Dose distribution histograms of the procedure groupings (Figure 3.1, 3.2 and 3.3);
- Dose distribution of examinations with 30 or more entries (Table 3.1);
- Diagnostic and interventional procedures that delivered the 10 highest skin doses to individual patients (Table 3.2);
- Histogram of the dose distribution of the renal arteriogram (Figure 3.4);
- The 10 diagnostic and interventional procedures with the highest dose to the population (Table 3.3); and
- Histogram of the 10 highest total dose diagnostic and interventional procedures to the population (Figure 3.5).

Figure 3.1 demonstrates the dose distribution histogram of the different procedures of the arterial outflow group.

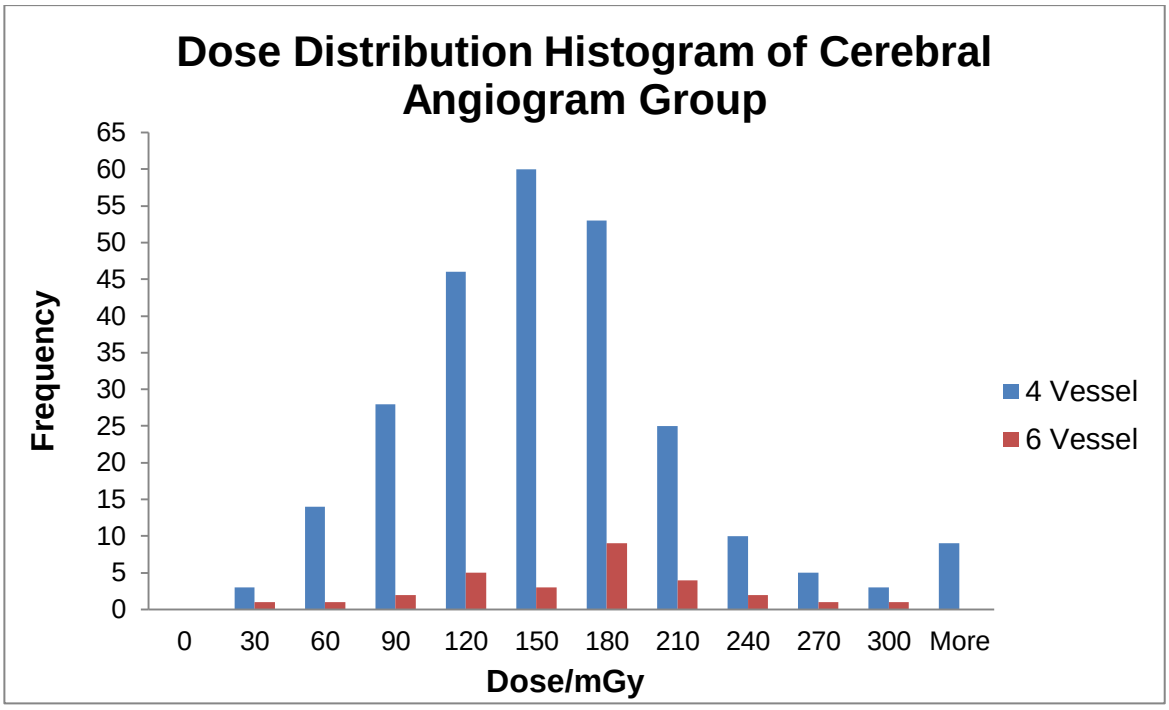


TBO=Trans-brachial outflow; TFO=Trans-femoral outflow; mGy=milli-Gray

Figure 3.1: Dose distribution histograms of aorta grams, trans-brachial and trans-femoral outflow studies, indicating that grouping could be done into the arterial outflow group according to distribution (n=663).

Figure 3.1 shows that the data are not a symmetrical (Gaussian) distribution. For this reason percentiles were used, namely upper (75th percentile / 3rd quartile) and lower (25th percentile) quartile values. The dose distribution was split into bins according to a specific dose range in intervals of 10 mGy. The frequency indicates the number of times a certain dose value was received by patients during this procedure. The most frequently performed procedure in this group during the study was the TFO (n=530). The median and 3rd quartile values are the best descriptors for highly skewed distributions (Vañó et al., 2013).

Figure 3.2 demonstrates the dose distribution histogram of the different procedures of the cerebral angiogram group.

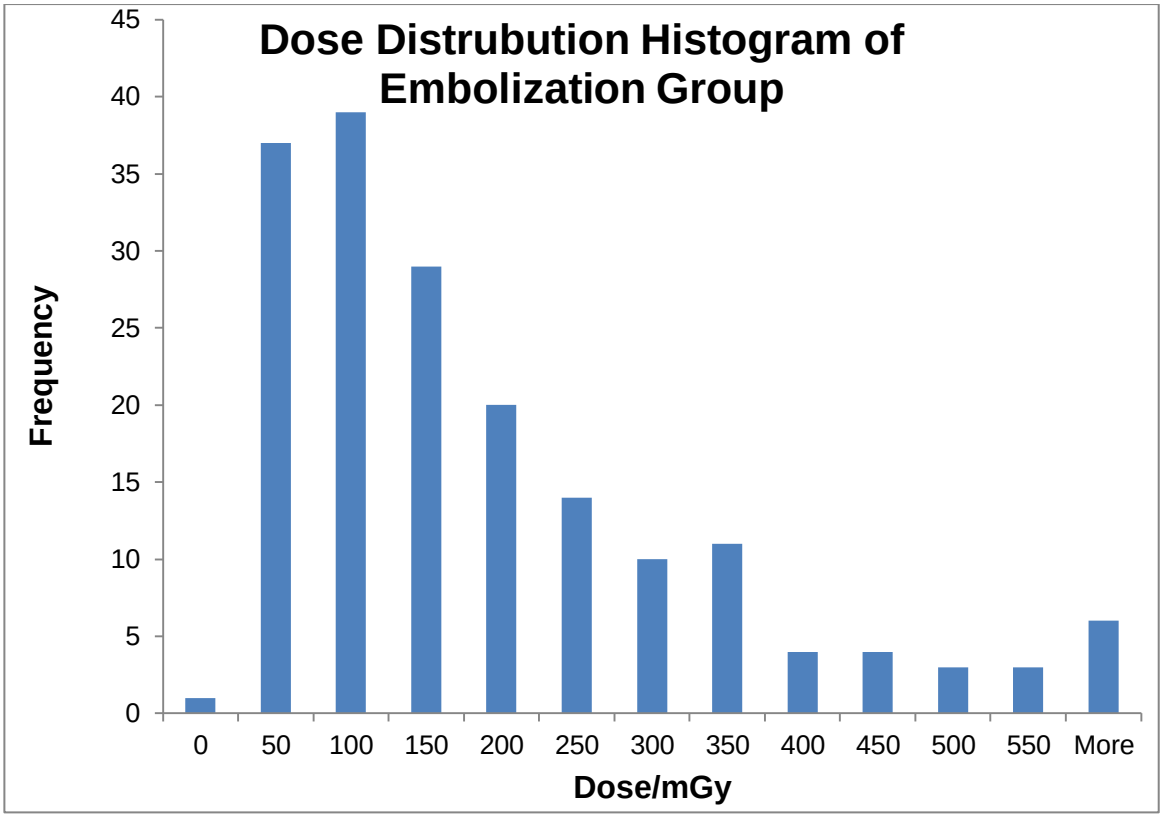


mGy=milli-Gray

Figure 3.2: Dose distribution histograms of four- and six-vessel studies indicating that grouping could be done into the cerebral angiogram group according to distribution (n=287).

The four-vessel angiogram was performed most often during the study period (n=257), and the highest number of procedures received skin doses between 150 mGy to 180 mGy. This distribution can fit in with a normal distribution, as the mean dose received was 144 mGy.

Figure 3.3 demonstrates the dose distribution of the different procedures of the embolization group. This group comprises 16 different procedures and the individual procedures are not indicated as with the other grouped procedures. The grouping was done to obtain a larger sample size as some of the embolization procedures are not performed regularly.



mGy=milli-Gray

Figure 3.3: Dose distribution histogram of the grouped embolization procedures (n=180).

The majority of these procedures received less than 200 mGy, but the embolization group had the highest mean value (176 mGy) of all the grouped procedures. This interventional procedure group was the least performed (n=180).

In Table 3.1 the maximum, lower, median and upper quartile skin doses for diagnostic and interventional procedure types that had 30 or more entries (patients) are listed. These procedures are ungrouped and are listed in a descending order according to the maximum dose.

Table 3.1 Dose values (mGy) for diagnostic and interventional procedures with 30 or more entries (n=2602)

Individual Procedure	**D/I**	**n**	**Lower Quartile (25^{th} %ile) in mGy**	**Median (50^{th} %ile) in mGy**	**Upper Quartile (75^{th} %ile) in mGy**	**Maximum dose in mGy**
Renal arteriogram	D	44	77	180	262	4 165
TFO	D	530	16	28	53	2 135
Percutaneous kidney stone removal	I	74	53	106	169	833
PTA leg/arm/renal	I	38	39	113	211	659
ERCP	I	263	12	24	38	630
Hickman line	I	59	3	4	9	613
Four-vessel angiogram	D	257	106	138	173	470
Nephrostogram/my	I	70	8	25	58	458
Embolization aneurysm	I	32	70	116	199	353
PTC follow-up	I	135	4	9	17	340
Permanent catheter	I	244	2	3	6	315
PTC	I	176	12	36	86	308
Six-vessel angiogram	D	30	117	156	191	288
Oesophageal dilatation	I	390	3	5	10	243

n=number of procedures; D=diagnostic; I=interventional; mGy=milli-Gray; %ile=percentile; PTC=Percutaneous trans-hepatic cholangiography; ERCP=Endoscopic retrograde cholangiopancreatography TFO=Trans-femoral outflow

Table 3.1 Continues

Individual Procedure	D/I	n	Lower Quartile (25th %ile) in mGy	Median (50th %ile) in mGy	Upper Quartile (75th %ile) in mGy	Maximum dose in mGy
Permanent catheter Revision	I	127	3	6	12	231
Arch of aorta	D	86	9	14	25	170
TBO	D	47	18	34	57	132

n=number of procedures; D=diagnostic; I=interventional; mGy=milli-Gray; %ile=percentile; PTC=Percutaneous trans-hepatic cholangiography; ERCP=Endoscopic retrograde cholangiopancreatography TFO=Trans-femoral outflow; TBO=Trans-brachial outflow

The procedures included in this table which had 30 or more entries, comprising six diagnostic and 11 interventional procedures. A renal arteriogram (diagnostic procedure) had the highest maximum dose to an individual patient, namely 4 165 mGy, and a median dose of 180 mGy. The second-highest maximum dose occurred during a TFO (2 135 mGy) with a median dose of 28 mGy. Both these two procedures' maximum dose exceeded the threshold value for deterministic effects, namely 2 000 mGy. The TBO (n=47) had the lowest maximum dose, namely 132 mGy.

The most frequently performed procedure was the TFO (n=530) – a diagnostic procedure. The six-vessel angiogram had the lowest number of examinations (n=30).

Note that all the 75th percentile values are much lower than the maximum dose value. None of the 75th percentile values exceeds 265 mGy, with the highest 75th percentile value at 262 mGy (renal arteriogram). The Hickman line has a maximum skin dose value of 613 mGy, a median of 4 mGy and an upper quartile value of 9 mGy. This reduction from maximum to upper quartile and median values is also true for nephrostogram/my; PTC follow-up; permanent catheter and permanent catheter revision; PTC; oesophageal dilatation; and arch of aorta.

In Table 3.2 the 10 procedures that delivered the highest maximum skin doses to the individual patient are listed. Four of these procedures have less than 30 entries (no. 3, 7, 8 and 9); however, these procedures need be taken into account since they were linked to some of the highest skin doses to patients in the study.

Table 3.2: Ranking of the 10 diagnostic and interventional procedures with the highest maximum dose to individual patients (n=1227)

Rank for max dose	Procedure	D/I	n	Lower quartile (25^{th} %ile) in mGy	Median dose (50^{th} %ile) in mGy	Upper quartile (75^{th} %ile) in mGy	Maximum dose in mGy	Rank for 75^{th} %ile
1	Renal arteriogram	D	44	77	180	262	4 165	3
2	TFO	D	530	16	28	53	2 135	9
3	EVAR	I	16	85	200	608	1 781	1
4	PTA leg/arm/renal	I	38	39	113	211	659	5
5	ERCP	I	263	12	24	38	630	10
6	Four-vessel angiogram	D	257	106	138	173	470	7
7	Embolization kidney/renal	I	9	153	185	326	406	2
8	Iliac stent	I	17	64	99	182	305	6
9	Renal stent	I	6	90	143	217	234	4
10	TBO	D	47	18	34	57	132	8

n=number of procedures; D=diagnostic; I=interventional; mGy=milli-Gray; %ile=percentile; TFO=Trans-femoral outflow; EVAR=Endoscopic vascular aneurysm repair; PTA=Percutaneous trans-luminal angioplasty; ERCP=Endoscopic retrograde cholangiopancreatography; TBO=Trans-brachial outflow

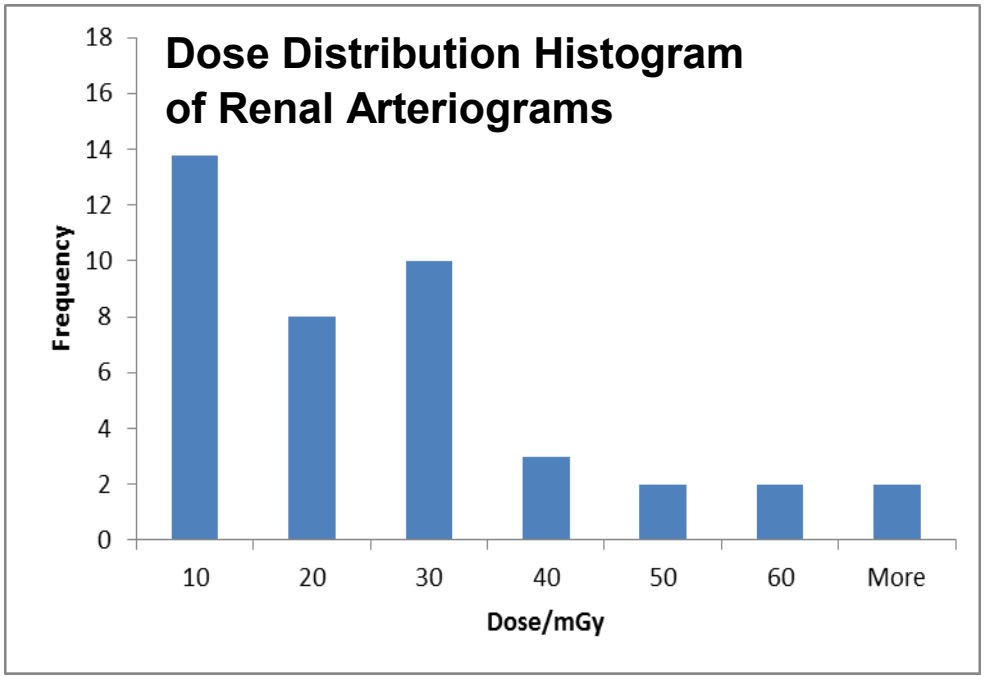
Procedures were ranked from 1-10 (according to the maximum skin dose). The maximum individual dose delivered during a procedure was 4 165 mGy for a renal

arteriogram, followed by a TFO at 2 135mGy and EVAR at 1 781 mGy. The threshold value for radiation injuries such as skin erythema (deterministic effect) is 2 000 mGy. The mentioned procedures exceeded (4 165 mGy and 2 135 mGy) or approached (1 781 mGy) this threshold value.

Procedures were also ranked from 1-10 for the 75th percentile value. In this column, an EVAR had the highest 75th percentile value of 608 mGy and an ERCP (endoscopic retrograde cholangiopancreatography) the lowest, namely 38 mGy. There is a large difference between the 608 mGy and the 57 mGy (TBO), 53 mGy (TFO) and 38 mGy (ERCP). It is noteworthy that none of the 75th percentile values for individual patients was near or even approaching threshold values for deterministic effects. An EVAR delivered the highest median dose of 200 mGy. A total of 75% of patients will receive doses in the 75th percentile range and less. For this reason, the 75th percentile values were also ranked from 1-10 in Table 3.2. An EVAR delivered the highest 75th percentile value of 608 mGy, followed by an embolization of renal artery/kidney at 326 mGy where, interestingly, these procedures ranked third to seventh for maximum dose to individual patients. A renal arteriogram ranked first for maximum individual dose and third in the 75th percentile range at 262 mGy. The TFO, a diagnostic procedure (n=530), was ranked second for the maximum dose (2 135 mGy) and ninth in the 75th percentile range (53 mGy). The reason for this difference between the upper quartile value and the maximum dose requires further investigation.

TFO, a diagnostic procedure, was performed most frequently (n=530) during the study period. The procedure performed least often was the renal stent, an interventional procedure (n=6), which ranked ninth for the maximum dose (234 mGy) and fourth in the 75th percentile range (217 mGy).

In Figure 3.4 the histogram of the dose distribution of the renal arteriogram procedures in this study is shown.



mGy=milli-Gray

Figure 3.4: Dose distribution histogram of renal arteriograms

From Figure 3.4 it can be seen that although the highest individual dose to an individual patient was delivered during a renal arteriogram (4 165 mGy), this was an isolated incident and resulted in the mean being much higher than expected from the 75th percentile and the median dose values (see Table 3.3). The remaining dose values delivered during a renal arteriogram are significantly lower than this outlier, as illustrated by the median dose of 180 mGy versus the 4 165 mGy of the maximum dose.

In Table 3.3, the procedures that delivered the 10 highest collective doses to the population are listed. The collective dose is the average (mean dose) multiplied by the number of patients, and gives an indication of the procedures with the highest dose to the population in the study. This is an important value for evaluating possible stochastic effects. The sum of average doses from the vascular suite and E-rooms was used for the collective dose.

Table 3.3: Ranking of the 10 diagnostic and interventional procedures with the highest summed dose to the population (n=1527)

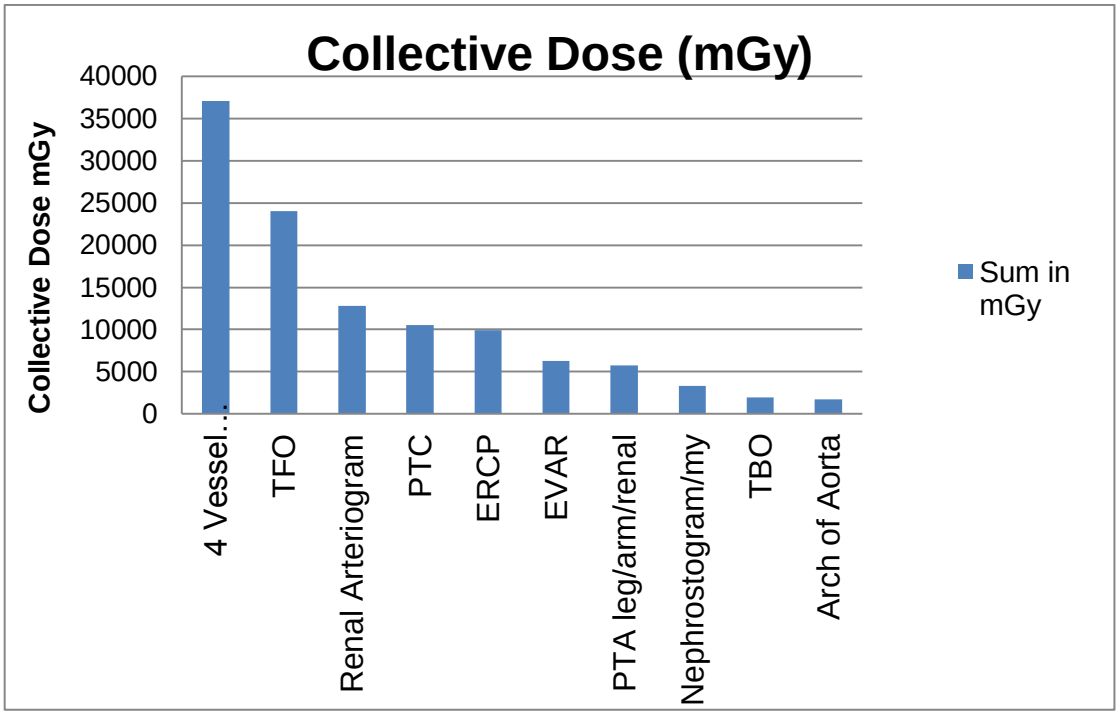
Rank for sum in mGy	Procedure	D/I	n	Lower quartile (25th %ile) in mGy	Median dose (50th %ile) in mGy	Mean dose in mGy	Upper quartile (75th %ile) in mGy	Sum in mGy
1	Four-vessel angiogram	D	257	106	138	144	173	37 025
2	TFO	D	530	16	28	45	53	23 996
3	Renal arteriogram	D	44	77	180	292	262	12 831
4	PTC	I	176	12	36	60	86	10 498
5	ERCP	I	263	12	24	38	38	9 948
6	EVAR	I	16	85	200	391	608	6 260
7	PTA leg/arm/renal	I	38	39	113	151	211	5 728
8	Nephrostogram/my	I	70	78	25	48	58	3 335
9	TBO	D	47	18	34	42	57	1 986
10	Arch of aorta	D	86	9	14	20	25	1 730

n=number of procedures; mGy=milli-Gray; D=diagnostic; I=interventional; %ile=percentile; TFO=Trans-femoral outflow; PTC=Percutaneous trans-hepatic cholangiography; ERCP=Endoscopic retrograde cholangiopancreatography; EVAR=Endoscopic vascular aneurysm repair; PTA=Percutaneous trans-luminal angioplasty; TBO=Trans-brachial outflow

From Table 3.3 the following procedures delivered the highest dose to the population: four-vessel angiogram (37 025 mGy), TFO (23 996 mGy), renal arteriogram (12 831 mGy), PTC (10 498 mGy) and ERCP (9 948 mGy). The collective doses of the other five procedures listed in the table were clearly lower.

When comparing the ranking of maximum skin dose to individuals (Table 3.2) and doses to the population (Table 3.3), the following procedures delivered both high doses to individuals as well as the population: renal arteriogram; TFO; EVAR; four-vessel angiogram; ERCP; and TBO.

Figure 3.5 demonstrates the distribution range between the collective doses of the top 10 procedures from the highest ranking procedure to the lowest ranking procedure.



TFO=Trans-femoral outflow; PTC=Percutaneous trans-hepatic cholangiography; ERCP=Endoscopic retrograde cholangiopancreatography; EVAR=Endoscopic vascular aneurysm repair; PTA=Percutaneous trans-luminal angioplasty; TBO=Trans-brachial outflow

Figure 3.5: Histogram of the 10 highest collective doses, diagnostic and interventional procedures, to the imaged population

The four-vessel angiogram delivered the highest dose to the population, and the arch of the aorta the lowest dose. This is in keeping with the formula for collective dose, where the mean dose is multiplied by the number of patients. The four-vessel angiogram was performed third-most frequently. The TFO was performed most often, but had the second-highest collective dose due to the fact that the mean dose (45 mGy) was lower than the mean dose for four-vessel angiogram (144 mGy). The arch of the aorta had the lowest mean dose (20 mGy), and was performed 86 times during the study period.

3.4 DISCUSSION

Grouping is especially useful in the embolization category (Figure 3.3), as some of these procedures were not performed as frequently and had less than 30 entries per group. Procedures in the embolization category are known to result in a high skin dose to the patient due to its complexity. It was meaningful to group the embolization procedures in order to obtain a bigger sample size. Although these procedures were performed less frequently, it can be seen that they deliver a high skin dose to patients.

From Table 3.1 it is seen that the renal arteriogram had the highest maximum dose to an individual patient, namely 4 165 mGy, and a TFO a dose of 2 135 mGy. Both these two procedures' maximum dose exceeded the threshold value for deterministic effects, namely 2 000 mGy. The maximum dose delivered during an EVAR, an interventional procedure, was 1 781 mGy. This dose is approaching the threshold value for radiation injuries such as skin erythema (deterministic effect) at 2 000 mGy.

In Table 3.2 the 10 procedures that delivered the highest doses to individual patients were listed. A renal arteriogram and TFO had doses exceeding threshold values for deterministic effects. An EVAR had the maximum value approaching the threshold value for deterministic effects. It must be stressed that the maximum skin dose delivered was probably a once-off occurrence (outlier) as the individual doses of the other procedures listed were significantly lower and did not exceed the threshold value for deterministic effects. The upper quartile values for the 10 procedures were significantly lower than the maximum values. As data were not discarded, the meaningful dose range would be between the 25^{th} and 75^{th} percentile values. This demonstrates where the central 50% of values lies. The most important value is the upper quartile value, as only 25% of all patients received more than this value (dose). The upper quartile value (75^{th} percentile) is of great importance when obtaining informed consent from a patient. This value will give the patient an indication of the dose they might receive.

"The collective effective dose for an individual is calculated as the sum of all individual effective doses over the time period being considered due to ionising

radiation" (http://en.wikipedia.org). The time period for this calculation was the study period (Chapter 2, section 2.5). Collective dose of the population is the product of the number of people exposed and the average dose (mean) (Kathren & Moeller (nd)). The number of individuals per procedure is specified in Table 3.3. This demonstrates that some procedures with high doses to individual patients are not performed as frequently, but still result in high doses to the population. It is intended that the values in the sum column reflect the dose delivered to the population for the sample we were studying and will be dependent on the number (n) of patients. As seen in Table 3.2, the procedure, embolization kidney/renal artery, was performed only nine times over the three-year period, but was ranked second in the 75th percentile value.

It is reassuring that all the upper quartile values shown in Table 3.3 are significantly lower than the response threshold value for deterministic effects of 2 000 mGy. It is interesting to note that in the procedures with the top 10 maximum doses, four of the procedures are diagnostic procedures and six interventional procedures. The top two maximum dose procedures are diagnostic procedures.

As mentioned earlier, establishing DRLs was not part of this study. Dose ranges for diagnostic and interventional procedures are rarely published and the only way to compare the research site values with that of values generated at other sites is by comparing it to documented DRL values. Table 3.4 demonstrates the maximum doses received at the research site compared to Swiss DRLs and DRL values from the literature in a paper titled "Adult Reference levels in Diagnostic and Interventional Radiology for Temporary Use in Switzerland" (Aroua et al., 2004). These Swiss DRLs were established during the 1998 nationwide dosimetric survey on exposure. A second survey in 2003 focused on dose-intensive fluoroscopic examinations from five university hospitals. Eight diagnostic and interventional examinations were investigated with the aim of establishing a set of provisional DRLs for diagnostic and interventional examinations performed in Switzerland, based on average patient doses. The DRLs for Switzerland and the compared DRLs from the literature consulted during the study of Aroua et al. (2004) were established based on average patient effective doses multiplied by 1.5. The DRLs obtained were rounded to the nearest whole number. The DRLs for the research site were calculated in the same way, also rounded to the nearest whole number, for comparison purposes.

Table 3.4 Comparison of DRLs for corresponding fluoroscopic procedures of the research site and Swiss values (Research site DAP=mean DAPx1.5) (Aroua et al., 2004, p. 293)

Procedure	D/I	Switzerland DAP (mGy.cm²)	Literature DAP (mGy.cm²)	Research site DAP (mGy.cm²)	Research site 75th %ile DAP (mGy.cm²)
ERCP	I	220 000	19 400	44 000	39 000
Cerebral angiography	D	50 000	102 000	169 000	138 000
Renal angiography	D	160 000	139 000 -265 000	175 000	262 000
Abdominal angiography	D	90 000	92 000	109 000 (TFO)	53 000
Biliary drainage/PTC	I	215 000	103 000 - 184 000	70 000	86 000
Angioplasty	I	14 000 - 155 000	74 000 - 108 000	90 000	211 000
Abdominal embolization	I	478 000	123 000	277 000 (Renal)	326 000

D=diagnostic; I=interventional: DAP=Dose area product; mGy.cm²=milli-Gray centimetres squared; ERCP=Endoscopic retrograde cholangiopancreatography; TFO=Trans-femoral outflow; PTC=Percutaneous trans-hepatic cholangiography

The DRL value for ERCP at the research site is higher than the value from the literature (the literature column values are from the abovementioned article), but much lower than the Swiss values. The reason for this phenomenon can also be the fact that as in Switzerland, ERCPs at the research site are mainly a therapeutic (interventional) procedure. Being a therapeutic procedure, it requires longer fluoroscopy times due to the complex nature. Diagnostic ERCPs or equivalent examinations are currently being performed mostly by using other modalities (non-x-ray) such as MRI (Aroua et al., 2004).

The DAP values for cerebral and abdominal angiography at the research site exceed the DAP values for both Switzerland and values from the literature. A possible

explanation for these higher values at the research site will be discussed in Chapters 4 and 5. Since there is no clearly defined abdominal angiography group, the closest comparable procedure for abdominal angiography in the current study is the TFO group, as it not only images abdominal vessels, but also the lower extremities. This could also explain the higher value. Renal angiography at the research site's DAP value is higher than the value for the Switzerland study, but well within the DAP range from the literature. Biliary drainage/PTC, angioplasty and abdominal embolization DAP values are lower than the Swiss DAP values and compare well to literature values. The lower values might be attributed to the interventionists performing these interventional procedures. In the mentioned study, there is no clearly defined abdominal embolization group; for this reason, the renal embolization group was used for comparison.

A comparison between the doses delivered to the patients at the research site and reference dose values from The National Patient Dose Database (NPDD) (Hart, Hillier & Wall, 2009) is listed in Table 3.5. This database comprises data collected from 316 hospitals in the United Kingdom (UK) over a five-year period ending 2005. These values are based on the third quartile values of the mean patient doses. The doses at the research site were rounded off to the nearest whole number. These were the only vascular diagnostic or interventional procedures listed in the database that corresponded to procedures performed at the research site.

Table 3.5 Comparison of dose-area product (DAP) of the research site, UK and international values for corresponding fluoroscopic procedures (Hart, Hillier & Wall, 2009, p. 9)

Procedure	D/I	Mean national reference doses for the UK DAP per exam (mGy.cm²)	Mean DAP values at research site per exam (mGy.cm²)	Mean DAP values at other European countries per exam (mGy.cm²)
Biliary drainage/intervention	I	50 000	47 000	
Hickman line	I	3 000	13 000	
Nephrostomy	I	14 000	37 000	
Oesophageal dilatation	I	11 000	4 000	
Oesophageal stent	I	25 000	13 000	
Femoral angiography	D	33 000	72 000	Germany 85 000 Switzerland 210 000

D=diagnostic; I=interventional; DAP=Dose area product; UK=United Kingdom; mGy.cm²=milli-Gray centimetres squared

At the research site all the procedures have lower DAP values, except for the Hickman line, nephrostomy and femoral angiography. However, when local mean DAP values for femoral angiography (72 000 mGy.cm²) is compared to mean DAP values from Germany (85 000 mGy.cm²) and Switzerland (210 000 mGy.cm²), this value is lower (Hart, Hillier & Wall, 2009, p. 11).

3.5 CONCLUSION

The results of this part of the study showed that selected procedures, such as renal arteriogram and TFO, have exceeded the threshold value for deterministic effects (see Table 3.1). It is thus necessary to evaluate each patient's dose after completion of the procedure to determine whether the threshold value for deterministic effects was approached or exceeded in order to inform the patient, radiologist and referring clinician about possible skin injuries. The maximum dose distributions showed that the two highest dose procedures were diagnostic, namely renal arteriogram and TFO, followed by the highest interventional dose procedure – an EVAR.

The 10 highest dose procedures to individual patients and the population were identified (Table 3.2 and 3.3). These specific high dose procedures identified require optimisation. Considerations must be made to determine possible dose adjustments to lower these doses. In the current study renal arteriograms, TFOs, EVARs, four-vessel angiograms and ERCPs are the procedures that delivered high doses to individual patients and the population. By optimising these procedures' doses at the research site the greatest effect will be seen to both individual patients, but especially to the population, as these procedures are performed most often.

It is interesting to note that the top 10 highest dose procedures to the population consist of five diagnostic vascular procedures and five interventional vascular procedures. The top three highest doses are diagnostic procedures, followed by five interventional procedures. This can be explained by the following calculation: Diagnostic procedures are performed more often (n), which results in a high population dose. Interventional procedures are not performed as often (n lower), but can deliver a high dose to the patient due to the complex nature of the procedure. Subsequent to the dose ranges and identification of high dose procedures in this chapter, further evaluation of factors that influence dose will be discussed in Chapter 4. The fluoroscopy equipment characteristics and the BMI of the patient's relationship to dose were evaluated.

CHAPTER 4
FACTORS INFLUENCING FLUOROSCOPIC DOSE

4.1 INTRODUCTION

In the previous chapter, dose distribution and ranges for procedures at the research site were determined, and specific high dose procedures to an individual patient and the population were identified. This section will deal with the third objective of investigating the factors that influence radiation dose during diagnostic and interventional procedures.

Factors that can influence patient fluoroscopic dose include, among others: dose and time; field size (area); patient size; distance and scatter; complexity of the case; skill of the radiologist performing the procedure; and fluoroscopy equipment characteristics (Molyvda-Athanasopoulu et al., 2011). Trueb et al. (2005) conducted a study to define the DRLs for fluoroscopic high dose procedures in Switzerland. It was concluded that although the frequency at which fluoroscopic x-ray examinations are performed is low; these procedures contribute considerably to the overall collective dose of medical exposure. The high doses during fluoroscopic interventional procedures have the potential to induce deterministic effects and the risk of radiation-induced cancer, a stochastic risk, can also be significant (Bleeser et al., 2008). In children, radiation doses will vary greatly depending on the age, gender, body mass, body thickness and cooperation of the child (Hiorns, Saini & Marsden, 2006).

In a study by Bor et al. (2005), an increase in radiation dose during fluoroscopic procedures has been observed, as these cases become more complex. This increase can be attributed to the use of lateral x-ray tubes (dual plane fluoroscopy), long screening times, numerous radiographic frames and using electronic magnification (Bor et al., 2005). As previously stated (Chapter 1, section 1.2.4), doses from interventional procedures vary greatly due to their complexity and

numerous other factors, such as patient anatomy, lesion characteristics, equipment used and operator experience. During fluoroscopically guided interventions, the equipment selection and configuration cause a wide variation in the doses delivered. High radiation doses might be caused by suboptimal or outdated equipment or incorrect equipment settings (Balter et al., 2011).

The primary objective of this part of the study was to evaluate the research site's overall dosimetric performance during diagnostic and interventional vascular procedures. A comparison of doses for similar procedures performed in the two different venues, namely the vascular suite and E-room (newer technology), was done.

A secondary objective of this part of the study was to demonstrate the correlation between the body mass index (BMI) value of the patient and how this value relates to the dose received. BMI is the mass of an individual in kilograms divided by the square of the individual's height in meters, given in units of kg/m^2 (Body Mass Index, 2014). Fluoroscopic dose rates are influenced by a patient's body mass as the dose output increases with increasing beam attenuation due to increased patient mass (IAEA, 2010). BMI is a scaled measure of the relative size of the patients; the attenuation of the x-ray beam is possibly more reliably related to the thickness or mass of the patient rather than the scaled mass. A tall person may have a BMI of 24, but may still cause greater attenuation and will require a high entrance dose; thus, BMI may not always be an accurate measure to predict the dose that will be received. Although the method of having the beam attenuation directly related to the thickness of the patient may be more useful to typical practice, as mentioned the aim of this study was not to determine DRLs. It was decided to use the information available (weight and height) to determine whether there is a valid correlation between BMI and radiation dose received. For the purpose of this study BMI will be used as a measure, as the circumference of the patients was not measured.

In this chapter, two of these factors are investigated, namely fluoroscopy equipment characteristics, and BMI's relationship to dose. A comparison was made between radiation doses delivered by an image intensifier system and doses delivered by flat panel detector technology. The relationship between a patient's BMI value and the

dose they received was also investigated. In Chapter 5 the relationship between the level of experience of the practitioner performing the procedure and the dose received by the patient will be investigated and discussed. This chapter will focus on the comparison of flat panel detector technology with an older image intensifier unit and the correlation of BMI's influence on dose.

4.2 ASSESSING RELATIONSHIP OF DOSE WITH LEVEL OF IMAGING TECHNOLOGY AND PATIENT BMI

To achieve the objective, the methodology described in Chapter 2 was followed. Additional information collected included an indication of which room the study was performed in, namely the vascular suite or E-room. A comparison was made between the doses of a number of similar procedures and grouped procedures (as discussed in Chapter 3) that were performed in the two fluoroscopic rooms at the research site. These doses were delivered by the Siemens Multistar 180° Multispace Swivel in the vascular suite and the Siemens AXIOM Artis in E-room.

In Table 4.1 the specifications of these two units are listed according to the manufacturer's documentation and user manuals (Siemens, 1997 & Siemens, 2004).

Table 4.1: Comparison of manufacturer specifications for vascular suite and E-room

Specifications	Vascular Suite	E-room
Manufacturer	Siemens	Siemens
Model	Multistar 180° Multispace Swivel	AXIOM Artis DMP
Tube	Megalix125/40/82CM-121W 3 phase	Megalix CAT/CAT Plus
Maximum mA	320 mA small focus 656 mA large focus 320 mA for 1sec max	Exposure: 640 mA at 125 kV Continuous operation: 1 000 mA at 80 kV
Maximum kV	125 kV	125 kV
Detector type	Image intensifier	Amorphous silicon with CsI scintillator flat detector
Installation date	August 1997	March 2007
DAP meter	Diamentor dose-area product meter (PTW, Freiburg, Germany) fitted to the under couch tube assembly	Dose measuring chamber for Card Collimator. Measuring chamber in primary collimator for measuring and display
DAP meter unit display	cGy.cm²	µGy.m²
Image intensifier formats/zoom options (Field diameters in cm)	40, 28, 29. 14	48, 42,32,22

mA=milli-Ampere, kV=kilo-Volt, CsI=Cesium Iodide, cGy.cm²=centi-Gray centimetres squared; µGy.m²=micro-Gray metres squared

The BMI values were calculated from patients who were willing (Appendix G) and able to be weighed and measured during a six-month period (1 August 2008 to 31 January 2009). A total of 136 useful BMI values was gathered over this period. These values were used to see how BMI relates to the radiation dose received. The correlation between BMI and dose received was grouped similar to that described in Chapter 3 (section 3.3), namely arterial outflow group, cerebral angiogram group and embolization group.

4.3 DOSE CORRELATION RESULTS

The results will be displayed in tables and graphs in the following sequence:

- Summary of statistics for all diagnostic and interventional procedures performed in the vascular suite and E-room (Table 4.2);
- Comparison of mean DAP values of TFO procedure performed in the vascular suite and E-room (Table 4.3);
- Mean DAP value distribution column for procedures in the vascular suite and E-room (Figure 4.1);
- Comparing dose values with BMI to dose values without BMI (Figure 4.2);
- Dose received versus BMI values for the arterial outflow group (Figure 4.3);
- Dose received versus BMI values for the cerebral angiogram group (Figure 4.4); and
- Dose received versus BMI values for the embolization group (Figure 4.5).

In Table 4.2 the mean and median dose (mGy) and DAP (mGy.cm^2) values are listed, as well as the maximum DAP values (mGy.cm^2) for all diagnostic and interventional vascular procedures performed in the two rooms. This table does not give an indication of the spread of data (range), as the first and third quartile values were not calculated.

Table 4.2: Dose and DAP value comparison of diagnostic and interventional fluoroscopic procedures performed in vascular suite and E-room (n=3073)

Type of procedures	**Room**	**n**	**Mean DAP mGy.cm²**	**Mean dose mGy**	**Median DAP mGy.cm²**	**Median Dose mGy**	**Maximum DAP mGy.cm²**
Diagnostic	Vascular	885	**77 776**	83	6 576	54	630 120
	E-Room	247	**86 424**	68	4 071	27	3 415 200
Interventional	Vascular	1 874	**33 815**	51	764	13	741 020
	E-Room	67	**51 590**	72	1 520	28	1 396 586

n=number of procedures; DAP=dose area product; mGy.cm²=milli-Gray centimetres squared; mGy=milli-Gray

More diagnostic and interventional vascular procedures were performed in the vascular suite (885+1874). Despite the smaller number of procedures performed in E-room, the mean DAP value was higher than in the vascular suite for both diagnostic and interventional procedures (86 424 and 51 590 mGy.cm² respectively). After performing a T-test for the mean DAP values in the vascular suite and E-room

it was seen that the higher mean DAP value for diagnostic procedures in E-room is not statistically significantly higher (p=0.2). The higher mean DAP value for interventional procedures in E-room also seems not to be statistically significant higher (p=0.6). The median DAP value was higher for the diagnostic procedures in the vascular suite, but for the interventional procedures this value was higher in E-room. The maximum DAP value was higher in E-room than in the vascular suite for both diagnostic and interventional procedures.

The skin dose for the above procedures was calculated taking the field area during the procedure into consideration. The first outlier of 3 415 200 mGy.cm^2 was delivered during a TFO performed in E-room. A skin dose of 2 135 mGy was calculated for a field area of 40x40 cm. On closer inspection of the details of the outlier, it was seen that this procedure had been performed by a newly appointed registrar in E-room. This might be an explanation for the higher dose, as could be the fact that the procedure had been performed in the newly installed fluoroscopic room. The second outlier of 1 396 586 mGy.cm^2 was during an EVAR performed in E-room, with a calculated skin dose of 1 781 mGy for a field area of 28x28 cm. Upon perusal of the radiologist's report, it was stated that the EVAR (interventional procedure) had been technically difficult as the patient weighed 158 kg. The height of the patient was not documented; thus, unfortunately, the BMI value could not be calculated.

The mean dose (mGy) and the median dose (mGy) are higher for diagnostic procedures in the vascular suite. For interventional procedures the opposite is true, where both the mean and median dose (mGy) are higher in E-room.

In Table 4.3 a comparison of mean DAP (mGy.cm^2) values of the TFO procedures performed in vascular suite and E-room was made.

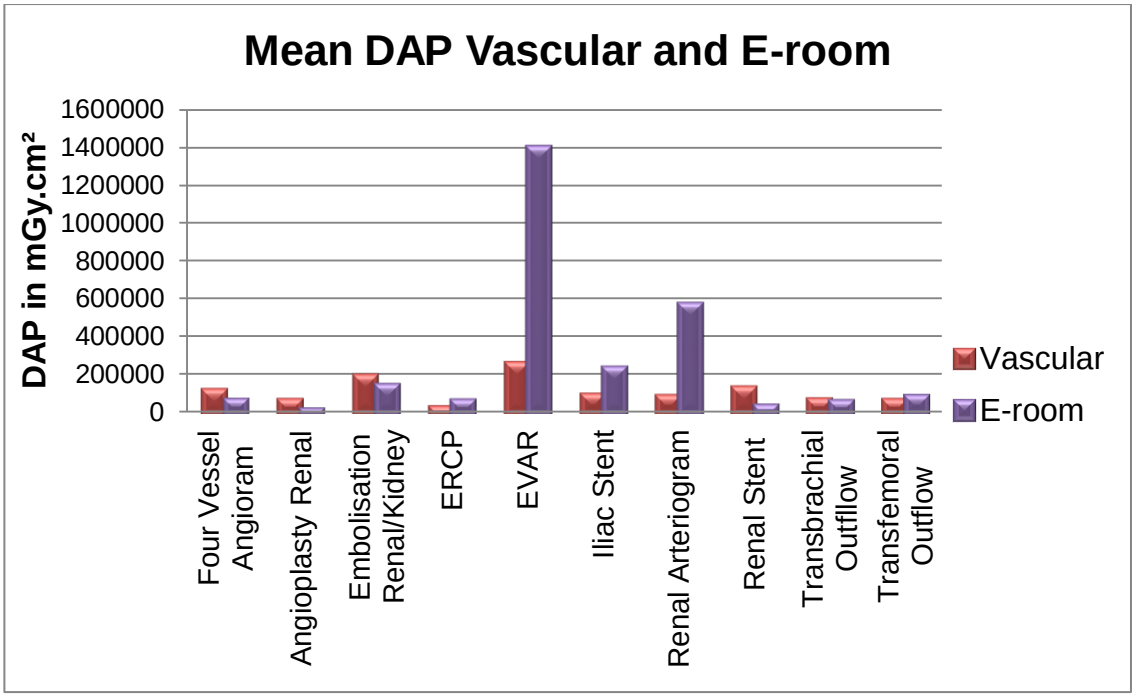
Table 4.3: Comparison of mean DAP (mGy.cm²) values of Trans-Femoral Outflow (TFO) procedures performed in Vascular Suite and E-room (n=530)

Trans-femoral outflow	Vascular Suite	E-room
Number of Procedures (n)	319	211
Mean DAP (mGy.cm²)	63 850	85 427

n=number of procedures; mGy.cm²=milli-Gray centimetres squared

The small number of procedures performed in E-room makes the comparison of the mean DAP values (mGy.cm²) between rooms difficult. The number of other procedures performed in E-room was too small to allow for meaningful comparison. The only meaningful comparison to be drawn was between TFOs performed in both vascular suite (n=319) and E-room (n=211), as there was also a larger number of these examinations performed in E-room. The mean DAP is higher in E-room (85 427 mGy.cm^2) than in vascular suite (63 850 mGy.cm^2), however this does not seem to be statistically significant (p=0.2). E-room was installed during the study period (March 2007); thus, the fact that the room's operation was not well-known at the time of the study could be a contributing factor. The protocol at the research site is that TFOs are performed in E-room by registrar radiologists.

Figure 4.1 demonstrates the comparison of average DAP readings (mGy.cm^2) received for diagnostic and interventional procedures performed in the two fluoroscopic rooms, namely the vascular suite and E-room.

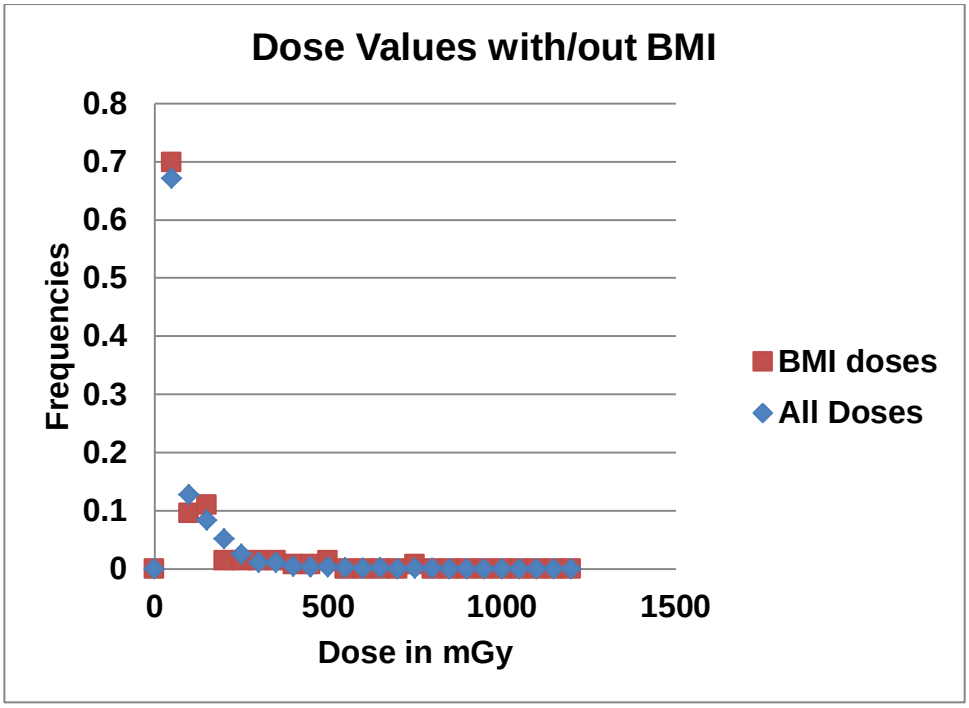


mGy.cm²=milli-Gray centimetres squared; EVAR=Endoscopic vascular aneurysm repair; ERCP=Endoscopic retrograde cholangiopancreatography

Figure 4.1: Mean DAP value distribution histogram for corresponding fluoroscopic procedures in the vascular suite and E-room

When comparing the average DAP readings between the vascular suite and E-room, ERCP, EVAR, iliac stent, renal arteriogram and trans-femoral outflow had higher DAP values delivered in E-room than in the vascular suite. The procedures in the vascular suite which had higher doses were not significantly higher compared to the dose differences of procedures which were higher in E-room, with the exception of the renal stent, which had a mean DAP in E-room of 35 160 mGy.cm² and a mean DAP of 129 780 mGy.cm² in vascular. The same reason for the higher DAP values in E-room, as mentioned for Table 4.3, could apply regarding the newly installed fluoroscopic equipment.

Figure 4.2 demonstrates a scaled graph which shows the dose values of patients with BMI values. A small number, when compared to the total amount, is comparable to dose values of patients without BMI values.

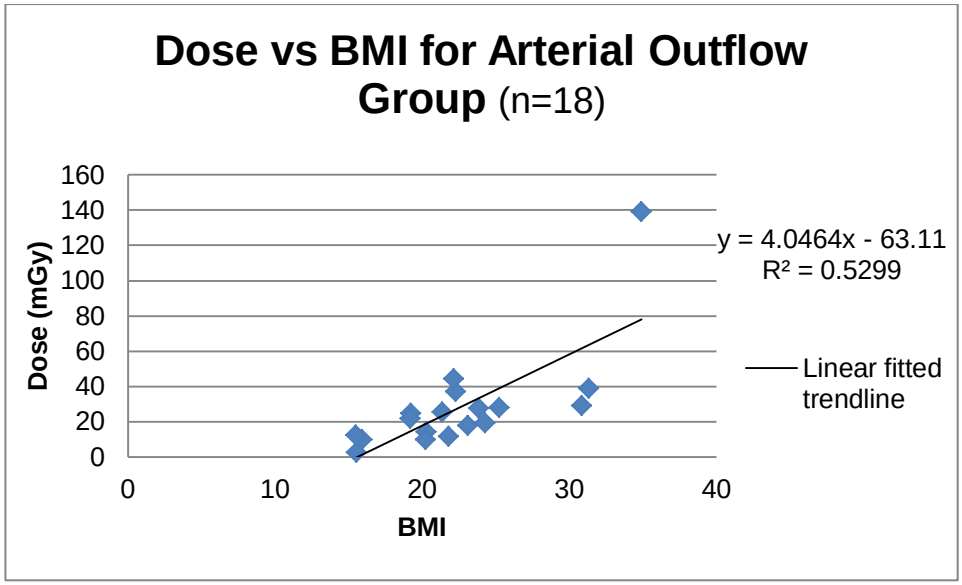


mGy=milli-Gray; BMI=body mass index

Figure 4.2: Scaled frequencies comparing the trend of dose values with BMI and dose values with/without BMI

The figure shows that the dose distributions for values with a known BMI and without BMI follow a comparable trend. A Mann-Whitney test was performed and only 136 of useful BMI values were obtained during the six-month period. This number is representative of the total of dose values after scaling.

Figure 4.3 demonstrates the relationship between patient BMI and radiation dose received for procedures in the arterial outflow group.

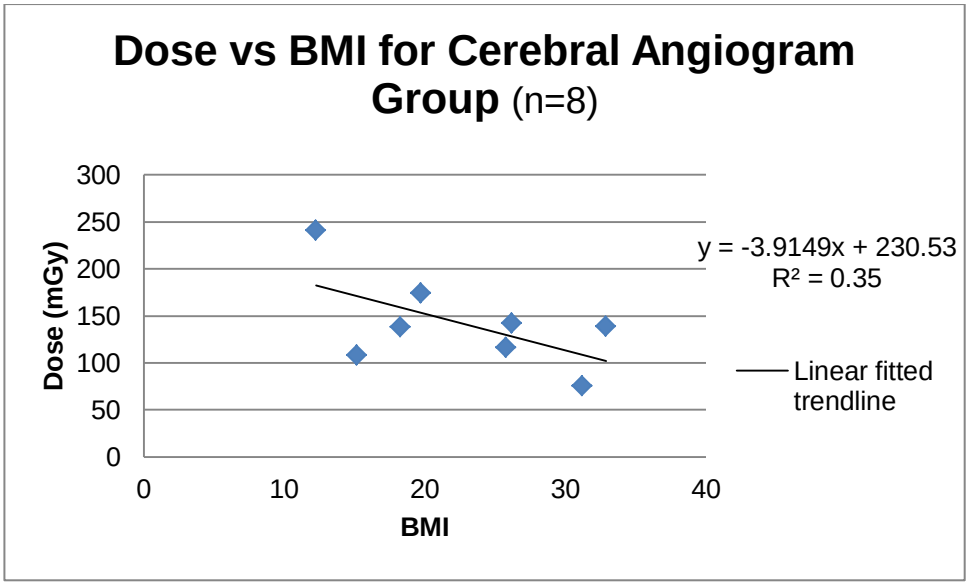


mGy=milli-Gray vs=versus; BMI=body mass index

Figure 4.3: Correlation of BMI value to the dose received for the arterial outflow group

The trend line shows an increase in dose with increasing BMI (Figure 4.3), the R^2 value of 0.5299 indicates that dose and BMI might be slightly related, as R^2 values between 0.5 and 0.9 are considered a strong correlation (Correlation Coefficient, 2014). The correlation is affected by outliers, and removing the possible outlier (139 mGy, BMI 35) the R^2 value changes to 0.4134, which indicates a moderate correlation. “The slope of a line can be defined as the ratio of the change in the y-value over the change in the x-value (y-value, 2014).

Figure 4.4 demonstrates the relationship between patient BMI and radiation dose received for procedures in the cerebral angiogram group.

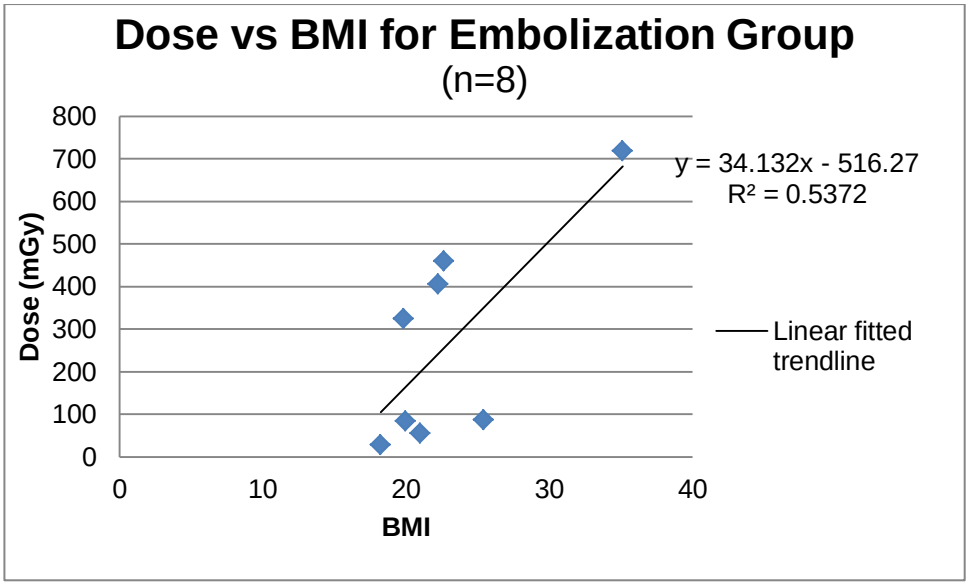


mGy=milli-Gray vs=versus; BMI=body mass index

Figure 4.4: Correlation of BMI value to the dose received for the cerebral angiogram group

The BMI and dose do not appear to have a clear relationship for the cerebral angiogram group. The R^2 value of 0.35 is indicative of a weak correlation; when the R^2 value lies between 0.1 and 0.5 it is considered that dose and BMI are weakly related (Correlation Coefficient, 2014). If the outlier of 241 mGy and BMI value of 12 is removed, the R^2 value changes to 0.078, which demonstrates an even weaker correlation between dose and BMI for a cerebral angiogram

Figure 4.5 demonstrates the relationship between patient BMI and radiation dose received for procedures in the embolization group.



mGy=milli-Gray vs=versus; BMI=body mass index

Figure 4.5: Correlation of BMI value to the dose received for the embolization group

It appears that BMI and dose are related for the embolization group; if the BMI increases, so does the dose received by the patient (Figure 4.5). From this graph, as well as the previous graphs, it is seen that all R^2 values demonstrate a strong correlation when the R^2 values lie between 0.5 and 0.9 (Correlation Coefficient, 2014). When the isolated outlier with a dose value of 719 mGy and BMI value of 35 is removed the correlation coefficient (R^2) changes to 0.0573, which is considered a weak correlation. This demonstrates that a single case has a considerable effect on the fitted trend line.

4.4 DISCUSSION

The main findings are the data in Table 4.2, which show that E-room with the newer technology had higher mean and maximum DAP values for interventional and diagnostic procedures. These higher DAP values must be investigated, as it is expected that the newer technology will deliver lower doses. In a study of Seibert (2006) on a question as to how much better flat panel x-ray detectors (FDP) are in comparison to image intensifier digital systems, the answer was “significantly better”. This improvement in image quality of the FDP can be attributed to “the lack of geometric distortion, little or no veiling glare, a uniform response across the field of

view and improved ergonomics with better patient access" (Seibert, 2006, p. 173). A decrease in patient dose can be achieved by improved quantum efficiency. Compared to the vascular suite, only a small number of procedures was performed in E-room, and the values of these procedures were, in two cases, much higher than the hundreds performed in the other room. A single EVAR (interventional procedure) was performed in E-room during the study period. The high dose in this case can be attributed to the technical difficulty of the procedure due to the patient's weight.

In Table 4.3 the mean dose in E-room is also higher than in the vascular suite. The majority of procedures, both diagnostic and interventional, were performed in the vascular suite. E-room was also used for fluoroscopic procedures such as Ba-swallows and Ba-enemas. These unexpected higher values in E-room might be attributed to the interventional and diagnostic procedure experience of the radiologist performing the procedure. Other specific patient problems, such as a grossly overweight patient, an extremely ill patient resulting in a complex case, or one with abnormal anatomy, could also contribute to higher DAP values. According to Miller, Kwon and Bonavia (2009) variation in radiation dose for individual cases can also be attributed to the level of practitioner training and experience which, will be discussed in Chapter 5.

Grewal and McLean (2005) compared the dose of a Siemens Axiom ArtisdBC flat detector and a Toshiba conventional system. It was found that DAP meter readings for the units showed little difference, and no differences were seen for the two most commonly performed procedures. The Siemens Axiom Artis features the Combined Applications to Reduce Exposure (CARE) package. It may be that the operators had not been fully aware of all the dose reduction features available in E-room following installation, and thus this could also be a possible explanation for these higher values when compared to the older image intensifier system used in the vascular suite. Seibert (2006) describes this type of learning curve of adjustment as orientation, leaving room for improvement during the implementation of new technological advances.

A study by Bor et al. (2005) showed that the use of smaller FOV options is more prevalent during interventional procedures, compared to diagnostic procedures. A

possible explanation for the higher mean and median dose (mGy) in the vascular suite for diagnostic procedures may be that smaller field areas were used during these procedures. “Differences in the irradiated field size may also cause the difference in radiation dose to patients” (Urairat et al., 2011, (http://www.biij.org). Dose is calculated by the following formula: DAP/area (cm^2) (Bushberg et al., 2012, p. 306). Table 4.1 demonstrates the two rooms’ various zoom (field diameter) options.

In Figure 4.1, ERCP, EVAR, iliac stent, renal arteriogram and trans-femoral outflow had higher average DAP readings in E-room than in the vascular suite. Although an increasing trend is seen for procedures in the arterial outflow group, the dose increase is relatively small for a large variation in BMI (Figure 4.2). From Figure 4.3 dose and BMI seems to be related and it seems that BMI was a contributing factor in the dose the patient received. Additional contributing factors such as the experience of the radiologist, and technical factors such as field size and type of x-ray spectrum (altered by filtration and tube potential), scattered radiation may also be responsible (Faulkner et al., (nd)). Figure 4.4 shows no clear relationship between BMI and dose in the cerebral angiogram group. The researcher concludes that the lack of a clear relationship between BMI and dose in this group is due to the fact that patients’ head circumferences do not vary much between high or low BMI values; the thickness of the body part radiated stays more or less the same. However, it should be noted that although a correlation is noted, BMI is not the only contributing factor to the increased dose, as these embolization procedures tend to be long and complex (Figure 4.5) (Bor et al., 2005). “In medicine, comorbidity is the presence of one or more additional disorders (or diseases) co-occurring with a primary disease or disorder; or the effect of such additional disorders or diseases” (Comorbidity, 2014). One could also speculate that increased BMI tends to lead to comorbidity factors, such as cardiovascular disease, diabetes and hypertension that could influence the complexity of the procedure and in turn the dose. An increased BMI of a patient has the potential of increased dose due to difficulty in the technical aspects of the procedure, such as overlapping skinfolds that can make it difficult to perform the puncture in the femoral region.

The National Radiation Protection Board (NRPB, 1992) proposes the use of the UK national protocol to obtain a robust measure of the average-sized patient. It recommends choosing patients where the mean mass of the patients lies within ±5 kg of 70 kg, and to exclude patients well outside the mass range of 70 kg ±10 kg. This method is applied when determining DRLs. This weight banding is to ensure that mean DAP values and related DRLs are representative of typical practice (NRPB, 1992). Another form of normalisation is using a normalisation factor derived from phantom measurements (Balter et al., 2011). The BMI values for patients in this study were not banded, as described. The BMI values for the measured patients represent the demographics of the research sample, as can be seen in Figure 4.2.

Killewich et al. (2010) state that higher radiation doses are required to penetrate a thicker body mass in, for example, obese patients. For every 4.5 to 5 cm of depth the radiation is reduced by a factor of two. As the body part becomes thicker, fluoroscopy units will adjust the dose automatically in order to ensure a certain level of brightness. Obese patients can receive up to four to ten times more radiation than thinner patients. In a review article done by Koenig, Mettler and Wagner (2001), it is seen that skin injuries are generally associated with overweight or heavyset individuals. It can be explained, as low energy x-ray radiation is used during fluoroscopically guided interventional procedures. This radiation is quickly attenuated at the surface where entering the patient. The absorption is largest in the dermal and epidermal tissues. These attenuated x-rays have low penetrability and result in greater dose rates in large patients; during steep angulations of the x-ray tube, this can result in radiation injuries.

4.5 CONCLUSION

The results show that E-room's mean DAP values were higher than in the vascular suite. This higher mean DAP value was only statistically significant for the interventional procedures. There were doses delivered in E-room which approached and exceeded the response threshold value for deterministic effects. This may not be significant considering the smaller number of procedures performed in E-room with marked outlier values. In cases where a procedure room, when compared to another procedure room, produces higher dose values, equipment should be

identified that requires investigation. Equipment repair, upgrade or replacement could be necessary if the dose reduction cannot be achieved without compromising image quality (Balter et al., 2011). Irrespective of using image intensifier systems or FDP systems, the operator always needs to be attentive of the equipment used and apply methods to reduce the radiation dose to our patients during the procedure (Seibert, 2006).

Figures 4.3 and 4.5 show a strong relationship between BMI and fluoroscopic dose received during this study. Since the groups are so small, single cases have a large effect on the fitted trend line. If one compares the R^2 value of the grouped procedures, there is a better correlation between BMI and dose during the arterial outflow and embolization group, when compared to the R^2 value of the cerebral angiogram group. As is evident by the marked outlier (Table 4.2) during the EVAR procedure in E-room BMI – or, in this case, weight – can definitely be a major contributing factor. Normally one would expect a patient with a larger BMI to receive a higher dose as a result of higher tube output to penetrate thicker tissue which will result in more scatter. The opposite can also be true where a normal size patient received a high dose resulting from longer fluoroscopy times and serial runs due to a complex procedure. One must not overlook the other factors influencing patient dose, such as the level of experience of the practitioner performing the procedure, angulations of the x-ray unit, distance and scatter.

When performing an interventional procedure on an overweight patient, standard dose reduction protocols apply, but it is even more important to ensure that dose rates are kept as low as possible. This dose reduction can be achieved by assuring that the image intensifier is kept as close to the patient as possible, and the x-ray tube as far from the patient as possible. Such action can prevent skin injuries to the patient (Koenig et al., 2001).

Increased exposure to patients during fluoroscopically guided diagnostic or interventional procedures can be facility-related or examiner-related. Facility-related factors can be improved by improving DSA equipment and putting protection systems in place. Examiner-related factors can be decreased by careful control of exposure parameters and the acquiring of procedural experience (Xu et al., 2011). In

the next chapter, another factor influencing the radiation dose, namely the relationship between the practitioner's level of experience and patient dose, will be investigated.

CHAPTER 5
INFLUENCE OF PRACTITIONERS' LEVEL OF EXPERIENCE ON PATIENT DOSE

5.1 INTRODUCTION

In the preceding chapters, dose ranges were determined, high dose procedures identified, an evaluation was made of the relationship that a patients' BMI has on dose, and older and newer technology were compared. In this chapter, and as part of a third objective of the study, additional factors, namely the technical knowledge and clinical experience of the practitioner performing the procedure that can also influence the dose, are presented. As previously discussed, interventional procedures are known to be of a complex nature, during which levels of radiation doses can reach and/or exceed threshold values for deterministic effects such as skin injuries.

Various factors may influence the radiation dose delivered during such a procedure. According to the final report on Dose Optimisation in Fluoroscopically Guided Interventional Procedures (IAEA, 2010) the experience of interventionists is an important factor in dose management. From this report it has been shown that even under well-monitored and controlled training conditions, significantly larger doses have been delivered to the patients by interventionists who are less skilled than others. Bor et al. (2008) describe the practice where a senior radiologist normally supervises the training of registrar radiologists for both diagnostic and interventional procedures. Similar supervision is the current practice at the research site. The study of Bor et al. (2008) concluded that it will take some time for an inexperienced radiologist to perform complex interventions alone, but with increasing experience, this time usually reduces. In the process, the dose to the patient will reduce as the practitioner's skills and knowledge increases. The validity of this conclusion will be tested for the research site in this chapter.

5.2 DEFINING CLASSES AND RELATIONSHIP TO DOSE

To attain the objective, the methodology as described in Chapter 2 was followed. At the research site there was non-randomised allocation of patients to the doctors. The level of the practitioners' experience was classified according to their qualifications and training as interventionist, consultant or registrar, as indicated on the data sheet. In Table 5.1 the classification according to the level of experience of the practitioner performing the procedures at the research site is described. The identity of the individual practitioner performing the procedure was also entered in the datasheet, as well as their class. If a consultant assisted a registrar, the procedure was allocated to the consultant and if an interventionist assisted a registrar or consultant, it was allocated to the interventionist. The radiation doses delivered by these three groups were evaluated and compared to similar procedures performed in both vascular suite and E-room.

Table 5.1: Classification of practitioners performing procedures at the research site

Class group	Description of Experience
Registrar	A junior doctor undergoing specialty training in the field of radiology on a recognised Radiology Training Scheme (Trainee radiologist, 2014).
Consultant	A qualified radiologist subspecialising and receiving specialised training in interventional radiology (Consultant radiologist, 2014).
Interventionist	A specialist radiologist in interventional radiology, who uses image guidance methods to gain access to vessels and organs and use the least invasive treatments, which previously would require surgery (Interventional Radiology, 2014).

The same grouping of procedures was used as in Chapters 3 and 4. The arterial outflow group and cerebral angiogram group were used for comparison. These two groups involved registrar radiologists (n=24), consultants (n=2) and interventionists (n=2) at the research site, and were compared for each of the classes of practitioners (Table 5.1). The mean dose delivered by each class group was

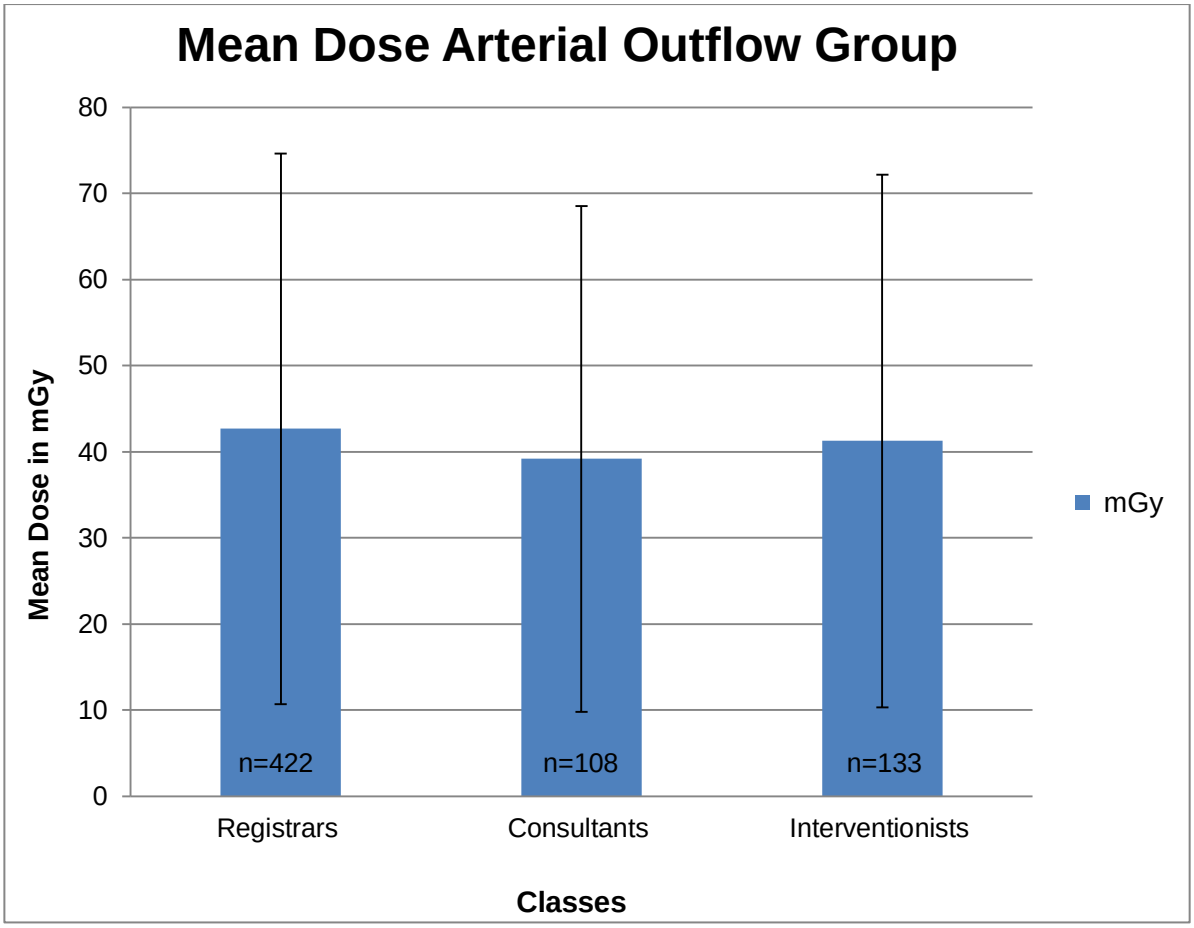
compared for both the arterial outflow and cerebral angiogram group. The mean dose for each group of doctors was calculated from the DAP and entry portal size of field (field area in cm^2) used for these procedures. Dose was calculated as DAP/field area (Bushberg et al., 2012, p. 306). The dose distribution for each of the class groups for the arterial outflow and cerebral angiogram group was also compared. The embolization group was not included in this comparison, as only interventionists and some consultants performed these procedures.

5.3 RESULTS

The results are displayed in tables and graphs in the following sequence:

- The mean doses for the arterial outflow group performed by the three classes of radiologists (Figure 5.1);
- Dose distribution for practitioners as box plots for the arterial outflow group (Figure 5.2);
- The mean doses for the cerebral angiogram group performed by all three classes of radiologists (Figure 5.3);
- Dose distribution for practitioners as box plots for the cerebral angiogram group (Figure 5.4);
- Relationship of DAP and registrar A's experience over time for the arterial outflow group (Figure 5.5); and
- Relationship of DAP and registrar B's experience over time for the arterial outflow group (Figure 5.6).

Figure 5.1 demonstrates the mean dose delivered during the arterial outflow group by the three classes of practitioners.

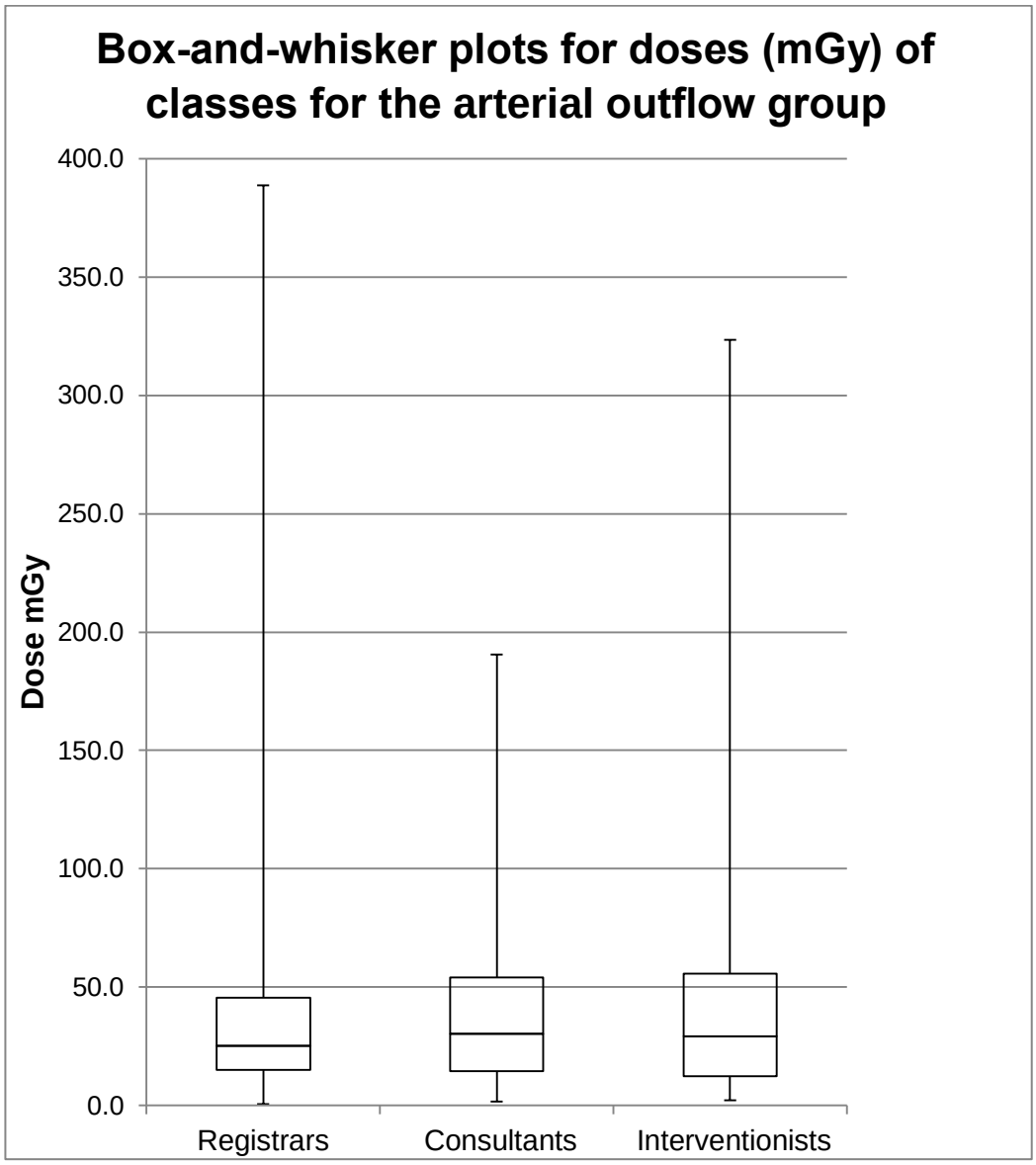


mGy=milli-Gray; n=number

Figure 5.1: Mean dose bar graph with 25th and 75th percentile error bars for arterial outflow group performed by consultants, registrars and interventionists

At the research site, registrar radiologists receive training on diagnostic vascular procedures such as trans-femoral/trans-brachial outflows and aorta-grams which compose the arterial outflow group. The registrars performed most of these procedures (n=422) followed the interventionists (n=133) and the consultants (n=108). From Figure 5.1 it is seen that the procedures that the registrars performed had the highest mean dose (43 mGy) followed by the interventionists (41 mGy) and the consultants (39 mGy). The ranges for the first and third quartile values correspond fairly well, indicating that there is little variation in the dose distribution of the various doctor classes. The negative error bars were calculated using the 25th percentile and the positive error bar was calculated using the 75th percentile. The overlapping error bars indicate no significant variation amongst the three classes.

Figure 5.2 demonstrates the dose distributions for the three classes of practitioners in the arterial outflow group as box-and-whisker plots.



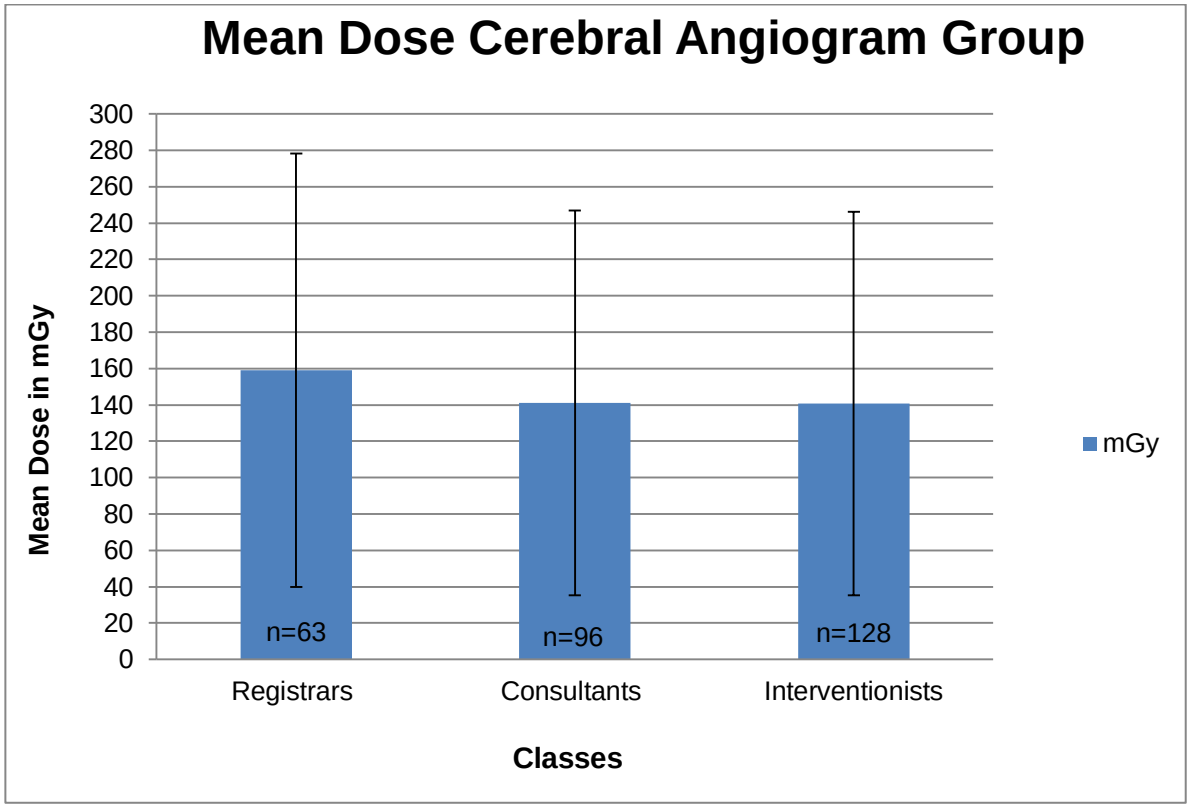
mGy=milli-Gray

Figure 5.2: Box-and-whisker plots of dose distributions for registrars, consultants and interventionists for the arterial outflow group

The horizontal line within the box indicates the median; boundaries of the box indicate the 25th and 75th percentile; and the whiskers indicate the highest and lowest values of the results. As can be seen from Figure 5.2, this is not a normal distribution. The distribution from the first to the third quartile dose values for all three classes of practitioners are more or less the same. The third quartile values to

maximum values of the registrars' and interventionists' distribution vary more, compared to that of the consultants. This is indicative of a positively skewed distribution, which can be expected as the procedures performed by the registrars had a slightly higher mean dose than the interventionists, which in turn had a higher mean dose than the consultants (Figure 5.1). A single outlier of 2 135 mGy in the registrars' data set was not included in the plot, as this was an isolated occurrence that deviated significantly from the rest of the data set.

Figure 5.3 demonstrates the mean dose delivered during the cerebral angiogram group by the three classes of practitioners.



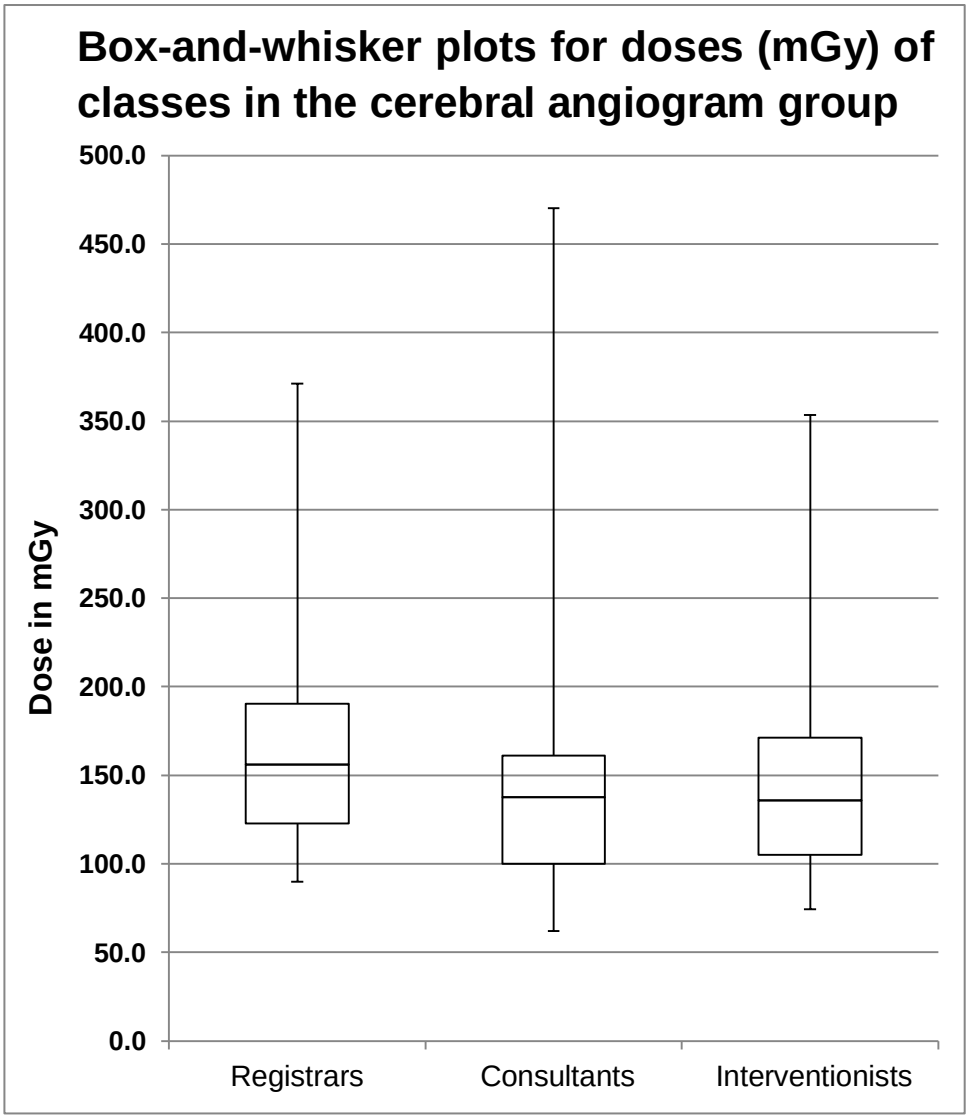
mGy=milli-Gray; n=number

Figure 5.3: Mean dose bar graph with 25th and 75th percentile error bars for cerebral angiogram group performed by consultants, registrars and interventionists

Registrar radiologists also receive training for cerebral angiograms, which is a diagnostic vascular procedure that includes four- and six-vessel angiograms. From Fig 5.3 it can be seen that the registrars delivered a higher mean dose (159 mGy) to

patients than the consultants (141 mGy) and interventionists (141 mGy), who achieved the same mean dose. The registrars performed the smallest number (n=63) followed by the consultants (n=96), while the registrars performed the most cerebral angiograms (n=128). The ranges for the first to third quartile correspond, indicating that there is little variation in the distribution of the various classes' doses.

Figure 5.4 demonstrates the dose distribution for the three classes of practitioners in the cerebral angiogram group as box-and-whisker plots.

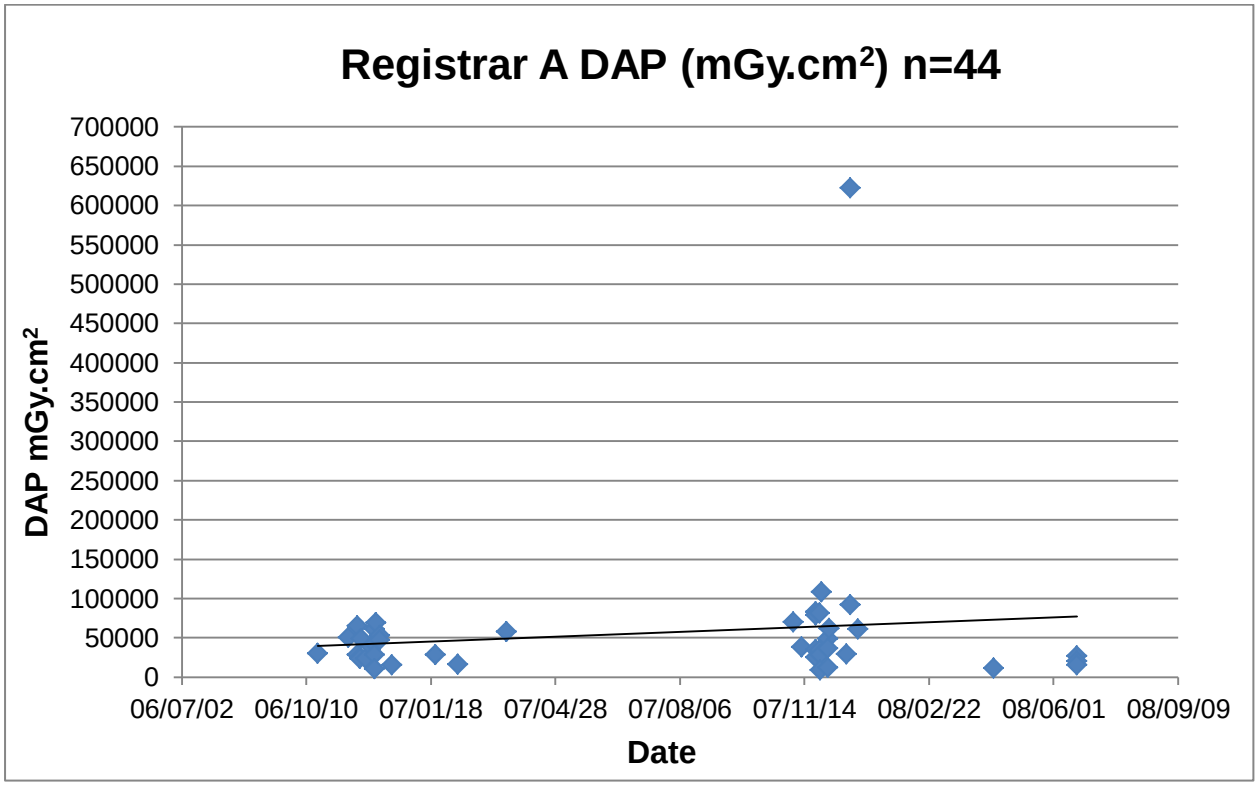


mGy=milli-Gray

Figure 5.4: Box-and-whisker plots of dose distributions for registrars, consultants and interventionists for the cerebral angiogram group

The horizontal line within the box indicates the median; boundaries of the box indicate the 25th and 75th percentile; and the whiskers indicate the highest and lowest values of the results. As can be seen from Figure 5.4, this is not a normal distribution. The distribution from the first to the third quartile values for all three classes of practitioners is more or less the same. The third quartile values to maximum values of the consultants' distribution vary more. The boxes for all three classes of practitioner are shifted towards the lower dose values, thus it is positively skewed.

Figure 5.5 demonstrates registrar A's DAP values for consecutive patients in the arterial outflow group over a time period.

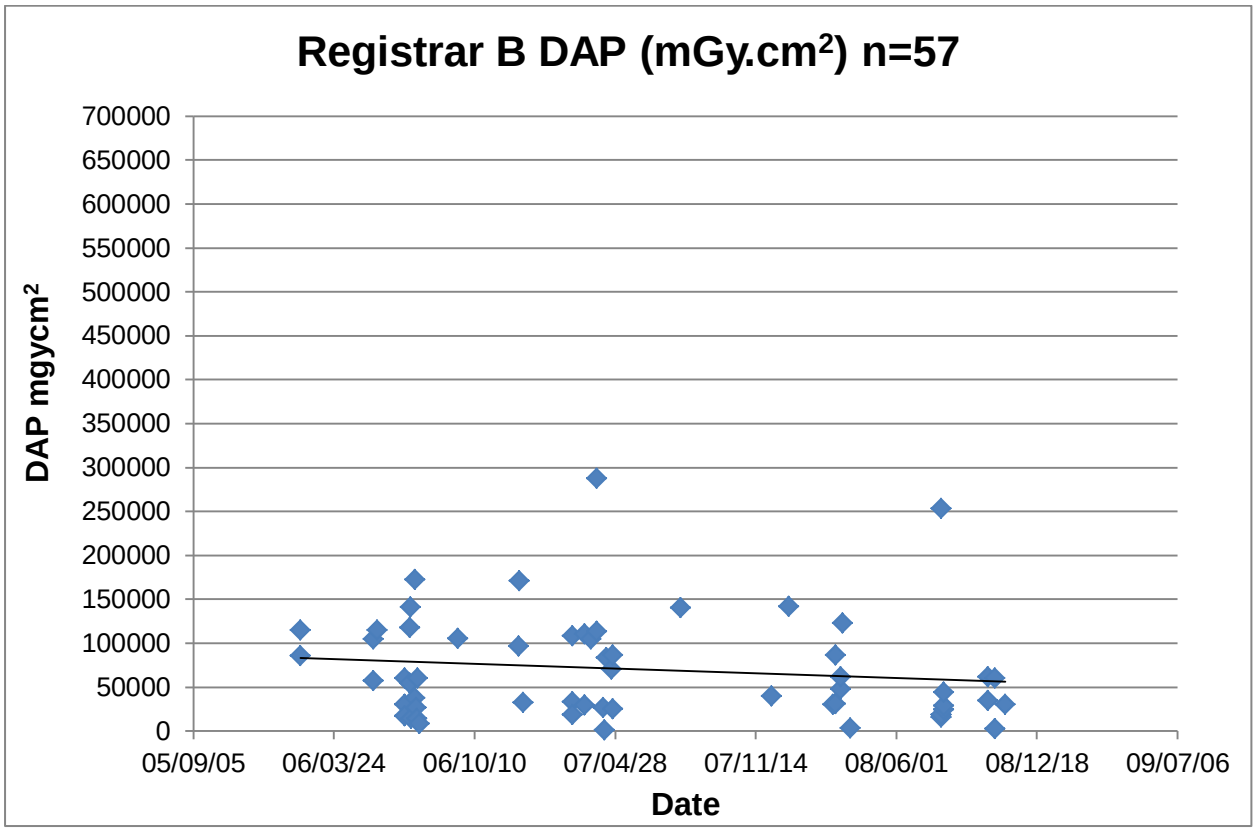


mGy.cm^2=milli-Gray centimetres squared

Figure 5.5: Relationship of DAP and registrar A's level of experience over time for the arterial outflow group.

Registrar A performed n=44 procedures during the three-year period of the study. There is not a large change in DAP values over the time period. As seen in Figure 5.5, there is one marked outlier (62 177 mGy.cm^2).

Figure 5.6 demonstrates registrar B's DAP values for consecutive patients in the arterial outflow group over a time period.



mGy.cm^2=milli-Gray centimetres squared

Figure 5.6: Relationship of DAP and registrar B's level of experience over time for the arterial outflow group.

In Figure 5.6 there is a slight decrease in DAP values over the given time period. This registrar performed n=57 procedures during the time of the study. It is interesting to note that despite the two outliers, the DAP values seems to have slightly decreased over the time period.

5.4 DISCUSSION

From Figure 5.1 it can be seen that the registrars delivered the highest mean dose (43 mGy) followed by the interventionists (41 mGy) and then the consultants (39 mGy). Although the consultants and interventionists performed a smaller number of these procedures, the mean dose to the patients during examinations performed by consultants and interventionists are not much lower than that of the registrars. A

possible explanation for this may be the fact that at the research site it is an unwritten rule that consultants and especially interventionists will perform the more complex cases, such as critically ill patients and patients with a high BMI value. These more complex cases usually take longer, which will contribute to the radiation dose the patient receives.

The skewed distribution in Figure 5.2 can be attributed to the level of experience of the practitioner. The higher maximum value of the interventionists can be due to the fact that they perform the more complex arterial outflow cases, which include the patients with a higher BMI value, which also has the effect of increasing the dose. Chapter 4 (Figure 4.3) demonstrates that there is a strong correlation between BMI and dose received in the arterial outflow group. The outlier with a value of 2 135 mGy mentioned previously exceeds the possible – maybe generally accepted – level that could be considered a threshold value for deterministic effects (ICRP, 2000). This was an isolated occurrence.

From Figure 5.3 the mean dose delivered during the cerebral angiograms performed by the registrars is significantly higher (159 mGy) than those of the consultants and interventionists (141 mGy). During the study period, the interventionists performed the majority of procedures in the cerebral angiogram group (n=128), followed by the consultants (n=96) and the registrars (n=63). The larger number of procedures performed by interventionists with a lower mean dose can possibly be attributed to their skill and experience. The selection of the carotid and vertebral arteries for imaging can be difficult if a patient has tortuous vessels and abnormal anatomy. In such cases, the skill of the practitioner performing the procedure plays a vital role in patient doses (Bor et al., 2008). Xu et al. (2011) suggests that registrars reduce radiation exposure during cerebral angiography by acquainting themselves with cerebral artery anatomy and training with catheter-wire manoeuvres.

The skewed distribution in Figure 5.4 can be due to the fact that consultants and interventionists perform more complex cerebral angiogram cases, compared to registrars.

In a study conducted by Xu et al. (2011), a comparison was made between the first 40 consecutive cerebral DSA procedures performed by 13 trainees on an Axiom Artis system (Siemens, Germany). These procedures were grouped as the first 20 and the second 20 procedures. According to Xu et al. (2011), a learning effect is present which is mostly seen for the first 20 procedures. This effect may be seen as shorter exposure time and lower radiation exposure with the gaining of performing experience by the trainee. The DAP, fluoroscopy time, number of cine frames, and procedure time were recorded. It was found that there was a marked decrease in DAP and fluoroscopy times as the trainees gained procedure experience. Procedure time and number of cine frames did not have a marked change. The higher radiation exposure during the procedure performed by a trainee is due to longer fluoroscopy times, searching for arteries, and manipulation of catheters and guide wires.

The results of this study motivated the decision to compare the two registrars who performed the most patients in the arterial outflow group over a period of time. This was done to evaluate if there was a noticeable learning effect present, as DAP values from registrars had the most room for improvement (reduction). However, there was no clear decrease in DAP (Figure 5.5) as is expected as a practitioners' level of experience and technical knowledge increased: the learning effect. This specific registrar was in the beginning of their training, as indicated by the commencement date of registrar training (November 2006) on employment records. A possible explanation can be that the registrar performed more complex cases during the last period of training and a further reduction in DAP values was not possible. This can be due to the turning point discussed by Xu et al. (2011) where the learning effect becomes insignificant.

When evaluating registrar B's performance (Figure 5.6) there is a slight decrease in DAP values over the time period. From employment records this registrar started training in September 2006, two months prior to registrar A. It must be stressed that there was non-randomised patient allocation to the doctors performing these procedures. Registrar B performed 13 more arterial outflow procedures for the duration of the study than registrar A. When comparing these two figures it is seen that registrar A did not perform these procedures as continuously as registrar B, who performed procedures in the arterial outflow group ongoing for the duration of the

study. This could be a possible explanation for registrar A's DAP values not decreasing over time: that they did not perform these procedures continuously due to roster allocations. However the change in DAP values for registrar B is almost negligible and no apparent conclusion can be made in this regard.

In order to evaluate the DAP values of the different classes of practitioner for both the arterial outflow group and the cerebral angiogram group at the research site, a comparison was made with a similar study conducted by Bor et al. (2008). During this study, a comparison was made between the DAP values delivered during cerebral and lower limb examinations performed by junior radiologists (n=7) and a senior radiologist. It was conducted at a single radiology department of a university hospital where junior radiologists are trained. A Siemens Multistar Plus TOP (Siemens, Erlagen), with 40, 28, 20 and 14 cm input field diameters was used for all the procedures – the same as one of the x-ray machines for the research site of this study. During the study at the research site values for both vascular suite (Siemens Multistar) and E-room (Siemens Axiom Artis) were pooled; however, most of the procedures were performed in the vascular suite. During the study of Bor et al. (2008), detailed documentation of FOV used, number of frames, fluoroscopy time, DAP for fluoroscopy and DAP for radiography (exposure) was done. For comparison purposes it will be assumed that a junior radiologist during his study is comparable to a registrar radiologist in this study, and a senior radiologist to an interventionist. Lower limb examinations are comparable to the arterial outflow group and cerebral examinations to the cerebral angiogram group.

In Table 5.2 a comparison is made between mean DAP received during lower limb and cerebral examinations at the research site and a study conducted by Bor et al. (2008).

Table 5.2: Comparison of mean DAP values of lower limb and cerebral examinations of the research site and study of Bor et al. (2008)

Average Values	Junior/Registrar Radiologists	Senior Radiologist/ Interventionists	Junior to Senior Ratio
Lower limb examinations:			
DAP $_{(mGy.cm^2)}$ - Bor et al.	140 (n=30)	240 (n=30)	0.58
DAP$_{(mGy,cm^2)}$ - Research site	680 (n=421)	660 (n=133)	1.03
Cerebral examinations:			
DAP $_{(mGy.cm^2)}$ - Bor et al.	890 (n=30)	840 (n=30)	1.06
DAP$_{(mGy.cm^2)}$ - Research site	1 270 (n=63)	1 100 (n=128)	1.15

DAP=Dose Area Product; mGy.cm^2=milli-Gray centimetres squared; n=number

The mean DAP values for the research site for both the lower limb and cerebral examinations for both the groups of doctors are higher than for the study conducted by Bor et al. (2008). At the research site the number of procedures (n) performed was more than that of the Bor et al. (2008) study, as they compared only 30 patients performed by each group of doctors in the lower limb and cerebral categories. The junior to senior ratios of the research site shows that registrar radiologists delivered a slightly higher mean DAP to their patients than the interventionists. They explained that the reason for the similar dose values for junior and senior radiologists during cerebral examinations was the use of standard acquisition protocols.

Standard acquisition protocols for both lower limb and cerebral examinations also exist at the research site. Bor et al. (2008) attribute the higher DAP values of junior radiologists to the frequent use of smaller FOVs (field diameter), which they use during placement or manoeuvring of the catheter and/or guide wire.

5.5 CONCLUSION

The objective of this chapter was to determine what effect the level of the practitioners' experience had on patient dose. The results indicate that the mean doses (mGy) delivered by registrar radiologists are slightly higher than that of the consultant and interventionists for both the arterial outflow and cerebral angiogram groups. As stated, normal practice at the research site would be that consultants and especially interventionists perform more complex cases and these are normally more

difficult, longer cases that will contribute to a higher radiation dose the patient receive (Faulkner et al., (nd)). In Figure 5.3 it is seen that although the number of procedures performed by interventionists is more, patients received a lower mean dose (mGy), this lower dose can possibly be attributed to their level of experience.

Xu et al. (2011) describes a learning effect that exits in the early stage of training, where a significant decrease in fluoroscopic time and radiation exposure is seen as the practitioner accumulates experience. There is a turning point, however, where this effect becomes less significant, normally after the first 20-30 procedures. This point is very important when improving the training programme for DSA procedures (Xu et al., 2011). In Figure 5.5 and 5.6, no clear decrease in DAP values is seen after 20-30 procedures that would have been indicative of the turning point as discussed by Xu et al. (2011). As this turning point was not clearly demonstrated, we argue that this could be indicative to the varied patient composition and complexity of cases at the research site. There was non-randomised patient allocation to the practitioners performing these procedures. Only the extremely complex cases would have been performed or assisted by either the consultant or the interventionist. This would possibly be the case only when the registrar could not perform the procedure alone.

During a comparison of DAP values between a study completed by Bor et al. (2008) and DAP values of the research site, it showed that these values are comparable. The mean DAP values at the research site were higher for both the registrars and interventionists for cerebral and lower limb procedures. The data from the research site that were compared with the data during Bor et al.'s study (2008) were more extensive, because more procedures were performed.

The fluoroscopic equipment used in the study conducted by Bor et al. was similar to the Siemens Multistar (vascular suite) at the research site. It must be noted that when compared, the Siemens Axiom Artis (E-room) delivered higher dose values than the Siemens Multistar, as discussed in Chapter 4 (Table 4.2). The higher DAP values at the research site can be attributed to this increase. It is important that during the junior radiologist training programme they learn the technical aspects of

the operating system and the relationship between equipment factors and patient doses (Bor et al., 2008).

In the next chapter, all the results obtained during this study will be critically evaluated. Discussion of the comparison done with studies published in the literature will be presented. Limitations experienced in this study will also be discussed and recommendations arising from this study will be made.

CHAPTER 6
CONCLUSIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

Interventional radiology is a fast developing field, playing an essential role in diagnosing and especially in treating patients with pathologies in nearly every organ system. Because interventional procedures use radiation as an imaging tool, this imaging modality needs to carry the responsibility for limitation, justification and optimisation. All role-players should try to optimise the dose to their patients and, in doing so, will in turn decrease the dose to personnel (Stecker et al., 2009). After a critical evaluation to all the information available in the literature, it was concluded that radiation workers at the research site were knowledgeable about radiation during fluoroscopically guided interventional procedures and documented the dose to the patient rigorously. But the critical evaluation of the dose, routine follow-up and optimizing of dose were lacking. This identified gap led to the setting of research objectives.

The objectives of the study were threefold. The primary objective of the study was to determine the doses and dose ranges to patients. A secondary objective was to identify specific high dose procedures to individual patients and the population; by using the results obtained, an awareness of dose levels and their relationship to radiation effects (injuries) will be created at the research site. A third objective was to investigate the factors influencing these doses.

6.2 ATTAINING THE RESEARCH OBJECTIVES

As stated, one objective of this study was to determine the dose distribution for specific diagnostic and interventional procedure types. Dose ranges for diagnostic and interventional procedures at the research site were not available.

6.2.1 Dose ranges for diagnostic and interventional procedures (2.4.1)

Similar diagnostic and interventional procedures were grouped to increase the number of patients in each group and thus facilitate a statistically significant comparison. In keeping with the objective, the dose distributions of these procedures were evaluated. The arterial outflow group was performed most often, followed by the cerebral angiogram group and the embolization group. The arterial outflow group and embolization group did not have a symmetrical distribution, while the cerebral angiogram group had a normal or bell-shaped distribution. DAP values were used as a dose measure (See Chapter 1, section 1.3). The DAP values of these mentioned procedures were used to calculate DRL values to compare with published values. The research site values for the three grouped procedures exceeded published values, as seen in Table 3.4. It must be noted that the grouped procedures at the research site were compared to procedures that were the most similar to those in the literature (Aroua et al., 2004).

6.2.2 Identifying specific high dose procedures which may require patient follow-up to individual patients and the population (2.4.2)

Procedures were ranked according to doses delivered (Table 3.2 and 3.3). Renal arteriogram, TFO, EVAR, four-vessel angiogram, ERCP and TBO were seen to be the procedures that delivered high doses to individual patients and to the population. The renal arteriogram (4 165 mGy) and TFO (2 135 mGy) had isolated occurrences where the suggested maximum level at which deterministic effects could be expected was exceeded, and thus radiation injury could realistically be expected to be caused to the patients. Upon closer inspection, the upper quartile values (75^{th} percentile) were significantly lower at 262 mGy and 53 mGy respectively. Reassuringly, none of the 75^{th} percentile values of any of these identified procedures were near to or approaching the response threshold value for deterministic effects. The generally used meaningful dose range lies between the 25^{th} and 75^{th} percentile values, which give an indication as to where the central 50% of dose values will be. Thus, this range encompasses the doses that could realistically be achieved without changing any of the equipment or the outcomes of the procedures being performed. The upper quartile value is important when obtaining informed consent from a

patient, as only 25% of all patients received doses higher than this value during the study period. The upper quartile value is often used in the literature as the DRL for that specific procedure. Nonetheless, optimisation of these procedures' doses will have to take place and the greatest effect will be seen to the population dose, as these procedures are performed more often.

In order to compare the research site's DAP values, some values were compared to documented values in the United Kingdom, Germany and Switzerland (only femoral angiography values for these countries were available) (Hart, Hillier & Wall, 2009) in Table 3.5. Biliary drainage, oesophageal dilatation and stent of the locally performed procedures delivered lower or on par radiation doses to that in the literature.

6.2.3 Comparison of doses for similar procedures performed in the two different venues, namely the vascular suite and E-room (newer technology) (2.4.3)

A further breakdown in evaluating the research site's overall dosimetric performance during diagnostic and interventional vascular procedures is a comparison of doses in the two different venues.

DAP values of similar procedures performed on older and newer technology were compared at the research site. The Siemens Axiom Artis in E-room was installed 10 years after the Siemens Multistar in the vascular suite. The newer technology had a flat panel detector, which was expected to deliver lower patient doses. This was not the case, and although a smaller number of procedures was performed in the room equipped with the new technology (E-room), the patient doses in this room were higher. At the research site, registrars would normally perform most of the diagnostic cases in E-room, namely the trans-femoral outflows and cerebral angiograms, as part of their training. As mentioned in Chapter 5, the level of experience can be linked to the dose a patient will receive. However, the interventional procedures performed by interventionists and consultants in E-room also had higher DAP and dose values compared to the procedures performed in the vascular suite (old technology). As stated, one of the explanations for the higher dose in E-room could be due to the fact that the operation of the room was not yet well known at the time

of the study. The operators might not have been knowledgeable about all the available dose reduction features of the fluoroscopic equipment.

6.2.4 Correlation of the BMI value of the patient relates to the dose received (2.4.4)

Various factors can play a role in the dose a patient will receive, including the body habitus of the patient. A third objective of the study was to demonstrate the correlation between the body mass index (BMI) value of the patient and how this value relates to the dose received. Weighing and measuring patients were not part of the departmental procedure at the research site at the time of the study. This practice was only done during the six-month period of the prospective part of the study. For the retrospective part of the study, no patient stratification according to BMI was made. This means that the retrospective data represent the present patient population of the research site (Kloeckner et al., 2012). The small number of useful BMI values that was obtained during the six-month period was representative of the total number of the dose values without BMI. The BMIs and dose during the arterial outflow (Figure 4.3) and embolization group (Figure 4.5) evaluation tended to indicate a strong relationship, but weakly related during the cerebral angiogram group (Figure 4.4). As discussed, BMI alone cannot be a measure of expected dose. The patient's thickness (area irradiated) plays a major role in beam attenuation and dose received.

6.2.5 The relationship of the practitioner's level of experience on skin dose (2.4.5)

Another factor that was evaluated was the effect that the skill of the practitioner performing the procedure had on the radiation dose received during procedures. The research design of this study was quantitative with a retrospective and partly prospective part (Chapter 2, section 2.5). There was no randomising in the retrospective part of the study and for the prospective part it was not known to the practitioners that the dose values of patients that they were performing procedures on would be analysed. As described by Kloeckner et al. (2012), this method of data collection represents the daily clinical routine and avoids bias, which is

advantageous. A true way to compare the impact of the practitioner's skill on dose is to make use of a prospective randomised trial with graded complexity, which would have ethical dilemmas (Kloeckner et al., 2012).

When comparing the mean doses delivered by the three classes of practitioner for the arterial outflow (Figure 5.1) and cerebral angiogram group (Figure 5.3), the registrars delivered higher mean doses to the patients than the consultants and interventionists. The distribution of these doses was skewed to the higher dose values (Figure 5.2 and 5.4). Training of registrars must include dose optimisation techniques and not only procedure protocol.

6.3 LIMITATIONS OF THE STUDY

6.3.1 Retrospective design

The retrospective design of a part of this study can be seen as a limitation. This part represents realistic values, as operators and physicians were not aware that they were being monitored. In a similar study by Pitton et al. (2012) this type of design avoids bias from any study and, conversely, if personnel are aware of dose monitoring, study-recorded DAP values can be too low.

6.3.2 Methodological errors

Although all reasonable measures were implemented to ensure the accuracy of the data captured, the following are limitations:

- The researcher was not employed full-time at the vascular suites during the research period and thus was not available to oversee the accuracy and classification of data entries during each diagnostic/interventional procedure. This was critical during the six-month period when weight and height were to be documented. As a result, only a small number of patients was weighed and measured.

- Power failures due to load shedding and power outages influenced the data, as the DAP meter resets to zero in case of a power failure; thus, the previous readings for that specific procedure were lost. The number of missing DAP meter readings due to these events were reflected in the total number of incomplete records (n=230) and, as a result, all these entries had to be excluded from the study.
- Systematic errors were kept as low as possible as a standard departmental procedure for documenting procedure type, and the patient detail used comprised patient information, procedure, doctor performing the procedure, DAP value and screening time.

6.3.3 Small number of procedures

Although a large number of procedures was performed over the three-year period, some were performed less often. During statistical analysis, it was found that the number (n) of some of the 76 types of procedures was too small to be statistically significant. There is a level of uncertainty whether the procedures had been correctly classified before the data were documented. This smaller number of procedures led to the grouping of similar procedure types. In the study of Pitton et al. (2012, p. 1492) it is stated that “the comparison of our DAPs to those in reports from the literature is challenging because of the differing grouping of interventions, which has the potential to completely alter the values.”

The research site is a training hospital. It was found that there were some practitioners, especially the registrars, who performed only a small number of procedures during the three-year period. This made the evaluation of how a practitioner’s level of experience influenced the dose that the patient would receive difficult. The number of dose values with known BMI values, although comparable to the rest of the data, is small. This makes the correlation between BMI and dose difficult.

6.4 RECOMMENDATIONS ARISING FROM THE STUDY

As evident from the data, patients receiving procedures such as renal arteriogram, TFO, EVAR, four-vessel angiogram, ERCP and TBO may be at risk of receiving high radiation doses.

6.4.1 Obtaining consent for identified high dose procedures

A patient must give consent to diagnostic and interventional procedures. But patients undergoing any of these aforementioned procedures must be specifically informed of possible radiation effects when obtaining consent the patient without causing unnecessary radiation phobia.

6.4.2 Radiation dose documentation for identified high dose procedures

Evaluate the radiation doses of all patients that had undergone any of these procedures immediately after the procedure. There is a function on most modern fluoroscopic equipment today which indicates where the patient's dose lies in relation to the response threshold for deterministic effects (2 Gy/2 000 mGy). At the research site, E-room had the dose indicator (if the weight and height of the patient has been entered), while the vascular suite (older technology) did not have such a function. If the fluoroscopic equipment is not equipped with such a function, this evaluation can be made by calculating the dose the patient received for the specific procedure. This calculation must be made from the DAP value/area (Chapter 2, section 2.10).

6.4.3 Follow-up for breeching of response thresholds

The result must be checked against the suggested maximum level for deterministic effects, namely how close to 2 000 mGy the patient dose was. If the response threshold value for radiation injuries had been exceeded or approached, the patient would require follow-up. The patient, radiologist and referring clinician should be notified of this dose and possible skin injuries that might occur. Previous fluoroscopy procedures must also be taken into account to determine the cumulative dose. At most interventional suites, patient dose reports are not automatically archived or

analysed (Vañó et al., 2013). Currently at the research site, patient dose values are recorded in a procedure book and entered manually onto the Picture Archiving and Communicating System (PACS).

6.4.4 Procedure allocation

The practice at the research site that senior practitioners perform more complex cases should be reiterated. Supervision by consultants and interventionists of registrars' procedures must be reinforced. They also need to step in or take over if a registrar is struggling with the technical execution of the procedure. These recommendations and the subsequent dose optimisation programme will ensure that doses to patients are reduced and are kept as low as possible.

6.4.5 Further research

As is evident by the results of this study, radiation doses to patients receiving interventional procedures can be high and subsequent radiation injuries can be a reality in complex procedures. Following the implementation of the proposed dose optimisation programme, further research needs to be conducted. The efficacy of the dose optimisation programme to reduce dose should be evaluated. A focused evaluation of dose optimisation of the identified high dose procedures to the individual patient and the public is required. Patient and staff doses are closely related and, in addition to patient doses, staff doses during interventional procedures can be investigated.

6.5 PROPOSED DOSE OPTIMISATION PROCEDURE PROTOCOL FOR THE RESEARCH SITE

From the above information it is necessary to compile a procedure with which radiation dose to the patient can be monitored and, where applicable, reduced. The data from this study will be used to initiate a dose optimisation programme. As stated in Chapter 1 (section 1.2.10-1.2.14) the SIR has released "Guidelines for Patient Radiation Dose Management" (Stecker et al., 2009), to be used for radiation dose management linked with interventional radiological procedures. The suggested

structure of these guidelines was used in the proposed dose optimisation programme for the research site. This dose optimisation programme will be recommended to the head of the radiology department. Departmental protocols for the research site will be revised as follows:

6.5.1 Pre-procedural planning protocol

Individual training: Radiographers and other personnel working in the interventional radiology suite will receive initial training in patient radiation management. Annual refresher training will take place in radiation management on the department's policies and government regulations. Both actions will be the responsibility of the radiation control officer in conjunction with the medical physicist of the radiology department.

Informed consent: Patients and, in the case of a minor, the parents or legal guardian will be informed by the radiographer of possible radiation risks before the procedure is performed. Specific high dose procedures have been identified (see Chapter 3, Table 3.2 and 3.3). The radiologist performing the procedure will question the patient regarding previous radiation exposure. This information will be brought to the attention of the radiologist and taken into account during the planning process of the new procedure.

Procedure planning: All relevant pre-procedure imaging available on the PACS at the research site must be reviewed, and not merely reports. These images may help in reducing procedure time, in reducing fluoroscopy time and the amount of fluoroscopic images needed, and in lowering the overall complication rates of the specific procedure. Non-invasive cross-sectional imaging modalities (magnetic resonance (MR) imaging and ultra-sonography etc.) must be used as part of the planning process with regard to access routes and device choices as proposed by Stecker et al. (2009).

Patient's BMI: Weigh, measure and document all able patients' weight and height. These values must be entered in E-room. This will result in the generation of an automatic dose indicator at the end of the procedure. This will be an easy measure

to see where a patient's dose lies in relation to 2 Gy (response threshold). This will also be used in the new vascular suite, as one needs to give an indication of a patient's weight (for example, <70 kg or >90 kg) which will be used for automated dose calculation.

6.5.2 Intra-procedural management protocol

Procedural radiation monitoring: The radiographer will monitor the dose during the procedure, using the table as in Chapter 1 (section 1.2.12, Table 1.1) as reference.

The doctor performing the procedure will take into consideration the radiation dose that the patient has already received, as well as the dose needed to complete the procedure. Bi-plane units' doses will be evaluated individually if the fields do not overlap, but will be added if they do.

Dose minimisation protocol for implementation at the research site: Radiographers and radiologists will receive extensive training, conducted by the radiation control officer and medical physicist, in the implementation of the dose minimisation protocol. This protocol will contain the following major points:

- Use the lowest pulse rate fluoroscopy mode where possible;
- Limit the fluoroscopy time;
- Limit the number of DSA frames and runs to the minimum;
- "Frame grab" where possible the fluoroscopy images and store fluoroscopic scenes (films) for documentation;
- Collimate to area of interest using virtual collimation;
- Elevate the table and keep the image detector as close to patient as possible and the x-ray tube as far as possible from the patient's skin;
- Limit the use of magnification; and
- C-arm angles should be varied during the procedure without interfering with the conduct of the clinical procedure.

6.5.3 Post-procedural care protocol

Dose documentation: The radiographer will record all patient and procedure data correctly. The radiographer and radiologist performing the procedure must evaluate and analyse patients' DAP values immediately after completion of the procedure for all procedures that involve fluoroscopy, but specifically for the identified high dose procedures. They will then determine if the patient will require follow-up by comparing the patient's dose to the table from the SIR guidelines (Chapter 1, section 1.2.11, Table 1.1). The radiographer will inform the radiologist when suggested maximum levels have been exceeded: if the patient's peak skin dose has reached 2 000 mGy, kerma-air-product has exceeded 500 Gy.cm², or the fluoroscopy time has exceeded 60 minutes. If there was any uncertainty of the dose the patient has received, a medical physicist would help evaluate the dosimetric aspects of that procedure. The radiologist will then schedule a follow-up with the patient's referring clinician.

Patient follow-up: All patients who received dose values that reached suggested maximum levels for deterministic effects need to be followed up. Follow-up is recommended even if the dose values were lower, but the same anatomical site has recently received radiation. Such a patient, who has received a noteworthy amount of radiation, will be given clear instructions for self-examination of the irradiated area. As part of the post procedural care protocol proposed for the research site, a patient who has received a substantial amount of radiation as indicated by the SIR guidelines during either a diagnostic or interventional procedure will be given instructions about the subsequent process (Appendix H) (Stecker et al., 2009). The patient will be required to inform the physician who performed the procedure or their referring doctor if skin changes occur within two weeks after the procedure. A scheduled follow-up examination with the referring physician will take place within 30 days of the procedure. The follow-up will take place irrespective of whether any reddening of the skin has occurred and whether or not the patient has informed the doctor.

6.6 CONCLUSION

Interventional fluoroscopic procedures are known for high doses, depending on a wide range of influencing factors. At the research site the doses of patients for vascular diagnostic and interventional procedures, although recorded, needed evaluation, and specific follow-up procedures are to be implemented. The purpose of this research project was to determine the dose ranges that can be expected for various procedures, taking into consideration all the major contributing factors influencing the patient's dose. The relationship of technology, BMI of the patient and the practitioner's level of experience to dose was evaluated.

From the literature, DRLs for simple x-ray examinations, such as chest and abdominal x-rays, act as a guidance level of what the doses at an institution need to be under normal conditions. It was found that determining DRLs for dose-intensive procedures that involves fluoroscopy, such as interventional procedures, is difficult. There are a few factors that lead to a wide distribution of patient doses; the complex nature of the procedures, loose definition of the examination, various techniques and protocols being used, and dose dependence on the radiologist's level of experience (Aroua et al., 2004) contribute to the wide distribution. A global concern is that interventional radiology is being performed more frequently and is becoming more complex, resulting in the risk of radiation injuries. Radiation protection and limiting or avoiding the occurrence of such effects are constantly being promoted and enforced by international and local governing organisations.

During the three-year study period at the research site, useful data were collected for 3 080 patients. When compared to documented international values, most locally performed procedures delivered lower or on par radiation doses; however, there were two isolated occurrences at the research site where the response threshold value for deterministic effects was exceeded. These two instances represent 0.06% of the total amount of useful data. When evaluating the 75^{th} percentile values, it was seen that all of these values were significantly lower. This value is to be used when obtaining informed consent. Comparing doses to individual patients and the population the renal arteriogram, TFO, EVAR, four-vessel angiogram, ERCP and TBO were seen to be the procedures giving higher doses.

In evaluating the factors that influence the dose to the patient the following was concluded:

E-room, although newly installed with flat-panel technology produced higher doses than in the vascular suite. Less procedure types were performed on fewer patients by fewer physicians than in the vascular suite. The BMI value of a patient, although a contributing factor, cannot be used as the only measure of expected dose. The registrars in the arterial outflow group as well as in the cerebral angiogram group delivered higher doses than the consultants and interventionists.

This specific research study set out to determine dose ranges for procedures performed in the vascular laboratories of Universitas Hospital for diagnostic and interventional procedures to determine specific high dose procedures to the individual and population, and investigate the relationship of specific factors on dose. Has this been achieved? The large amount of documented data over the tree-year period was used to determine dose ranges for most common procedures. This information will definitely be used as a starting point for assessment of doses at local level. These data will be used as baseline values, and although the setting of DRLs was not intended, it can be seen that the 75th percentile values can be used, even if only for comparison purposes, to determine if further optimization actions are needed. If optimization of doses is needed, these 75th percentile values can give an indication as to which doses need to be optimized first. Investigation-specific factors showed an interdependent and intertwined relationship with the dose the patient is to receive. The specific dose optimising programme will be recommended for implementation at the research site. The programme will give clear instructions to all involved personnel, from the pre-procedural planning phase and intra-procedural dose management to the evaluating of the dose that the patient received and follow-up procedure if necessary. The information from this study is a starting point for dose limitation and optimisation at the research site. The dose optimising and follow-up procedure proposed will ensure better informed clinicians, interventionists, radiographers and patients.

From our experience, after doing the research and in our environment (the research site), it was seen that multiple procedure types were performed on a varied

composition of patients. These ranged from paediatric to adult and with varying BMIs, by practitioners with different levels of experience on different types of equipment. Considering all this information, it was seen that the majority of radiation doses at the research site was significantly lower than the response threshold values for deterministic effects. However, radiation doses always need some optimisation, as is evidenced by the two dose values breaching the 2 000 mGy threshold level for skin injuries and the possibility of stochastic effects. This should be achieved by implementing the proposed dose optimising programme, which will create greater awareness amongst all role-players, including the patient.

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Appendix A

Poster of Pilot Study: Audit of Staff and Patient Doses in a General Vascular Laboratory

Presented at the 26th SAAPMB Congress

Appendix B

Information Entered On Data Sheet

Information entered on the data sheet:

Date of the procedure
Procedure x-ray number indicated in procedure book
UM number (unique identifier to the hospital)
Procedure performed
Diagnostic/Interventional procedure
DAP reading ($cGy.cm^2$/$\mu Gy.m^2$)
Screening time (s)
Doctor performing the procedure
Classification: Registrar/Consultant/Interventionist
Vascular Suite/E-room
Error (if data are missing/incomplete)
Height of the patient (m)
Weight of the patient (kg)
Body Mass Index (BMI) of the patient = (kg/m^2)

Appendix C

List of Procedures, Classifications of Diagnostic/Interventional and Field Area Sizes

NO	PROCEDURE	Diagnostic(1)/Interventional(2)	Field Area (cm^2)
1	Oesophagus Dilatation	Int (2)	20x20
2	PTC/Percutaneous Gastr	Int (2)	28x28
3	Four Vessel Angiogram	Diag (1)	28x28
4	PTC Follow-up	Int (2)	28x28
5	Perm Cath	Int (2)	28x28
6	ERCP	Int (2)	28x28
7	TFO/Limb arm/leg	Diag (1)	40x40
8	Aorta Angiogram	Diag (1)	40x40
9	Bronchial Artery Embolization	Int (2)	40x40
10	Chemo Embolization/ARF/TACE	Int (2)	28x28
11	Embolization AVM	Int (2)	28x28
12	Nephrostogram/Nephrostomy	Int (2)	28x28
13	Splenoportogram	Diag (1)	28x28
14	Sino gram	Diag (1)	28x28
15	PL Tube/Oesophagus stent	Int (2)	28x28
16	IVC Filter	Int (2)	20x20
17	Fine needle Aspiration/Drainage (Abscess)	Int (2)	20x20
18	TBO	Diag (1)	40x40
19	Renal Arteriogram	Diag (1)	20x20
20	Pelvis Arteriogram	Diag (1)	40x40
21	Carotid Arteriogram	Diag (1)	20x20
22	Arteriogram of the face	Diag (1)	20x20
23	Perm Catheter Brush	Int (2)	20x20
24	Six Vessel Angiogram	Diag (1)	28x28
25	Percutaneous Kidney Stone Removal	Int (2)	20x20
26	Removal of Pancreas tube/Carey Coons stent	Int (2)	40x40
27	Placing of Naso-duodenal tube/Feeding tube	Int (2)	20x20
28	Embolization Varico cele	Int (2)	20x20
29	IVC Gram	Diag (1)	40x40
30	Angioplasty leg/arm/renal	Int (2)	20x20
31	Hickman line/Revision line/Chemo Port	Int (2)	20x20
32	JJ catheter/Ante grade	Int (2)	20x20
33	Venogram	Diag (1)	40x40
34	Fistulogram/Fistulogram arm	Diag (1)	20x20
35	EVAR	Int (2)	28x28
36	Iliac stent/TFO & stent/Stent Femur	Int (2)	28x28
37	Occlusion Balloon Aneurism (subclavian)	Int (2)	20x20
38	Stent Carotid/Occlusion Carotid	Int (2)	20x20
39	Embolization Face (Haemangioma)/Nasopharynx angiofibroma/Hem back/parotid	Int (2)	20x20
40	Hepatic/Splenic Artery Embolization	Int (2)	40x40
41	Foreign Body Removal	Int (2)	28x28
42	Stent AV Fistula (subclavian)	Int (2)	20x20
43	Pressure Trans-femoral /Aorta/IVC	Diag (1)	40x40

44	Duodenal dilatation/stent/Colon stent	Int (2)	28x28
45	Drainage cyst kidney/ Follow-up	Int (2)	28x28
46	Arteriogram Spinal	Diag (1)	40x40
47	Sheath and catheter placing Brachial/Placing thrombolysis catheter	Int (2)	40x40
48	Embolization Fistula/Carotid/Dural fistula	Int (2)	28x28
49	Fine needle biopsy of para spinal tumour	Diag (1)	28x28
50	Streptokinase Follow-up	Diag (1)	40x40
51	Bronchial Arteriogram/ Pulmonary Arteriogram	Diag (1)	40x40
52	Embolization Forearm/lower leg	Int (2)	40x40
53	Cholecystostomy	Diag (1)	28x28
54	UAE	Int (2)	28x28
55	Embolization Aneurysm	Int (2)	28x28
56	Embolization Kidney/Renal	Int (2)	28x28
57	Lumbar Puncture under Fluoroscopy	Diag (1)	28x28
58	Selective Arteriogram	Diag (1)	40x40
59	Two Vessel Angiogram	Diag (1)	28x28
60	Fine Needle Aspiration	Int (2)	28x28
61	Abscess Drainage/Fluid collection/Percutaneous drainage	Int (2)	28x28
62	Replace Drainage catheter	Int (2)	28x28
63	Removal of Stent/Nephrostomy tube	Int (2)	40x40
64	Bronchial Stent	Int (2)	28x28
65	Stent Renal	Int (2)	28x28
66	Intussusception Reduction	Int (2)	28x28
67	Embolization nose bleed/Abdominal bleed	Int (2)	20x20
68	Port Block	Int (2)	28x28
69	Embolization Rectum/Pelvis	Int (2)	28x28
70	Rectum Stent	Int (2)	28x28
71	Venous Sampling	Diag (1)	28x28
72	Renin Levels	Diag (1)	28x28
73	Revise AV Fistula	Int (2)	20x20
74	Lumbar Artery embolization	Int (2)	28x28
75	Embolization Flank	Int (2)	28x28
76	Embolization mamma artery/subclavian	Int (2)	28x28

Appendix D

Ethical Committee Approval for the Research Study

Appendix E

Approval for study Universitas Hospital Head: Clinical Services

Appendix F

Approval for study Universitas Hospital Radiation Control Committee

Appendix G

Patient Consent to be weighed and measured

Appendix H

Post procedural patient information leaflet

Information Leaflet for Patient Follow-up:

Patient Name: _____ **Date:** _____

At the completion of your diagnostic and/or interventional procedure it was found that:

☐ During your procedure you did not receive a significant amount of radiation (x-rays). No specific follow-up will be required because radiation side effects are highly unlikely.

☐ During your procedure you received a significant amount of radiation (x-rays). Radiation side-effects are unlikely but possible. Please check your skin in the

_____ area for any sign of reddening or itching in two weeks' time or

Please call the X-ray department at (###) ### ####, to report if there is any sign of reddening of your skin to dr._____ .

You are required to come and see dr. _____ again on

_____ .

Appendix I

Abstracts of poster and paper presentations arising from this study.

AUDIT OF STAFF AND PATIENT DOSES IN A GENERAL VASCULAR LABORATORY (Poster Presentation)	26th South African Association of Physicists in Medicine and Biology (SAAPMB) Congress	6-8 June 2007
PATIENT RADIATION DOSES FOR VASCULAR EXAMINATIONS IN A GENERAL AND INTERVENTIONAL VASCULAR LABORATORY (Paper Presentation)	Faculty of Health Sciences Research Forum University of the Free State (UFS)	23-24 August 2007
HIGHEST DOSE VASCULAR PROCEDURES AT UNIVERSITAS HOSPITAL (Paper Presentation)	Faculty of Health Sciences Research Forum University of the Free State (UFS)	23 August 2012
DOSE DISTRIBUTION FOR VASCULAR PROCEDURES AT UNIVERSITAS HOSPITAL (Paper Presentation)	International Society of Radiographers and Radiological Technologists (ISRRT) 18th World Congress Helsinki, Finland	12-15 June 2014